HOME INTRAVENOUS ANTIBIOTICS FOR CYSTIC FIBROSIS

Marco T, Asensio O, Bosque M, de Gracia J, Serra C

Date of most recent amendment: 25 August 2000
Date of most recent substantive amendment: 07 July 2000

This review should be cited as: Marco T, Asensio O, Bosque M, de Gracia J, Serra C. Home intravenous antibiotics for cystic fibrosis (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2003. Oxford: Update Software.

ABSTRACT

Background
Recurrent endobronchial infection in cystic fibrosis requires treatment with intravenous antibiotics for several weeks, which is usually administered in hospital, affecting health costs and quality of life for patients and their families. It is not known whether patients receiving intravenous treatment at home have better or equivalent health outcomes, if costs are reduced or if it is preferred than in-hospital treatment. Home treatment requires training to patients and carers and usually needs a few previous days in hospital.

Objectives
To determine whether home intravenous antibiotic therapy in cystic fibrosis is as effective as in-patient intravenous antibiotic therapy and if it is preferred by patients and/or families.

Search Strategy
References to trials were obtained from the cystic fibrosis trials register held by the editorial base of the Cochrane Cystic Fibrosis and Genetic Disorders Group. Handsearching of the abstracts books of all Spanish Conferences on cystic fibrosis and the last European Conference (Stockholm, 2000) was carried out by authors.

Date of the most recent search of the Group's specialised register: April 2002.

Selection Criteria
Randomized controlled trials where home intravenous antibiotic treatment for patients with cystic fibrosis was compared with in-hospital intravenous antibiotic treatment, including adults and children with cystic fibrosis. All kinds of antibiotics and regimens administered intravenous were included.

Data collection and analysis
Three reviewers independently selected the trials to be included in the review, assessed methodological quality of each trial and extracted data using a standardised form. Because of several limitations, narrative synthesis was used at this stage.

Main Results
Seven studies were identified by the initial search. One study reporting results from a total of 17 patients aged 10 to 41 years with an infective exacerbation by Pseudomonas aeruginosa was included in the review. All their 31 admissions were analysed as independent events. Outcomes were measured at 21 days of follow-up after initiation of treatment. Home patients had fewer investigations performed than hospital patients ($p<0.002$) and general activity was higher in the home group. No significant differences were found for clinical outcomes, adverse events, complications of intravenous lines or line changes or time to next admission. Home patients received less low-dose home maintenance antibiotic.

Quality of life measures showed no significant differences for dyspnoea and emotional state, but fatigue and mastery were worse for home patients, possibly due to a higher general activity and need of support. Personal, family, sleeping and eating disruptions were less important for home than hospital admissions.

Home therapy was cheaper for families and the hospital. Indirect costs were not determined.

Reviewers' conclusions
The current evidence is restricted to one small study. It suggests that in the short term home therapy does not harm patients and in general reduces social disruptions. The decision to attempt home treatment should be based on an

individual basis and appropriate local resources. More research is urgently required.

This review should be cited as:
Marco T, Asensio O, Bosque M, de Gracia J, Serra C Home intravenous antibiotics for cystic fibrosis (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2003. Oxford: Update Software.

BACKGROUND

Cystic fibrosis (CF) is the most common fatal autosomal recessive genetic disorder in Caucasians. It is characterised by recurrent endobronchial infection leading to progressive pulmonary deterioration. This colonisation of the airways occurs, firstly with Staphylococcus aureus, and then with Pseudomonas aeruginosa (Davis 1996). This requires treatment with combination antibiotics, most of which need to be given intravenously for several weeks (David 1986) and until recently requires in general to be given as an in-patient. As the lung disease progresses, patients may require more frequent hospitalizations. This greatly increases health care costs and may adversely affect the patient's quality of life.

Home intravenous (IV) therapy in CF is a response to both increasing demand for hospital beds, and the need for treatment to interfere as little as possible with the patient's normal lifestyle and quality of life. Home IV therapy may also cut costs by avoiding hospital admission or reducing length of stay. Staying in hospital may be hazardous for patients with CF because of the risk of contracting Burkholderia cepacia, methicillin-resistant Staphylococcus aureus (MRSA), and other multiresistant organisms.

It is not known if patients receiving home IV have better or equivalent health outcomes compared with patients receiving in-patient care, whether the provision of home IV results in reduction in costs to the health service (Rucker 1974; Donati 1987; Davis 1990; Strandvik 1992; Pond 1994; Bosworth 1997), or whether patients prefer this form of treatment.

Home IV therapy with antibiotics are usually commenced for exacerbations of chest disease. They can begin in hospital or as an outpatient. They require the training of patients and their carers and suitable medical support.

OBJECTIVES

(1) To determine whether home IV antibiotic therapy in cystic fibrosis is as effective as in-patient IV antibiotic therapy, for exacerbation of lung disease.

(2) To determine whether home IV antibiotic therapy in cystic fibrosis is preferred by patients and/or families to in-patient IV antibiotic therapy.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomized controlled trials where home IV antibiotic treatment for patients with CF was compared with in-hospital IV antibiotic treatment. Studies were stratified by those where treatment was initiated in hospital but completed at home or those where all treatment was given at home, and by severity of exacerbations.

Types of participants

The review includes adults and children with CF diagnoses defined clinically and by sweat or genetic testing, including all ages and all degrees of severity, and who receive IV antibiotic treatment. All kind of antibiotics and regimens administered IV were included.

Types of intervention

Studies comparing home with acute hospital in-patient antibiotic therapy for patients with CF requiring IV antibiotic treatment. This includes interventions where the entire course of IV antibiotic is administered at home, either by the patient, their carer, or a health-care professional, as well as interventions where home IV follows an in-patient stay but

care professionals, as well as home IV where a variety of methods of support is offered by health-care professionals, including home visits and administration of the IV injections or infusions. Any duration of antibiotic courses were considered.

Types of outcome measures

(1) Lung function: change in percent predicted or absolute change in forced expiratory volume in one second (FEV1), or forced vital capacity (FVC). If other parameters are used, they were considered.

(2) Lung infection: conversion of sputum from culture positive to culture negative, reduction in CFU counts for P.aeruginosa and other microorganisms.

(3) Weight gain: absolute weight gain, change in % of ideal body weight, or weight standard deviation score.

(4) Clinical complications: any clinical complication including acquisition of new microbial infection with B.cepacia, MRSA or other organism, haemoptysis, pneumothorax, acute distal intestinal obstruction syndrome, development of diabetes mellitus during follow-up period. This does not include adverse events which are specified in point 11.

(5) Re-admissions: unplanned re-admissions and administration of additional antibiotic courses within three months, and within any time period during the follow up period, and time to next admission or next course of antibiotic treatment.

(6) Improvement of clinical score, by validated instruments.

(7) Mortality.

(8) Cost, if measured: (a) direct: stay in hospital, visits of/to general practitioner or hospital, community nursing services, drug costs, etc.; (b) indirect: work time lost for patients / parents, travelling expenses to/from hospital, any other support (for example, domestic aids), etc.

(9) Hospital days saved from the provision of treatment at home: days on treatment with home IV that would otherwise have been spent in hospital.

(10) Duration of treatment: less than 10 days or 10 days or more.

(11) Quality of life measures examined in patients and/or carers.

(12) Adverse effects related to the antibiotics including gastrointestinal symptoms, reduced appetite, abdominal bloating, urticaria and itching. Those associated with IV treatment such as thrombophlebitis, infection, number of change of IV lines required. Other adverse effects, if reported, will also be examined.

(13) Compliance with other treatment measures, such as chest physiotherapy, nutritional regimens, etc., if measured, by objective or subjective criteria.

It was planned to group outcome data into those measured at the end of the antibiotic course, one, three, six, twelve months and annually thereafter. If outcome data were recorded at other time periods then consideration was given to examining these as well.

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

See: Cochrane Cystic Fibrosis and Genetic Disorders Group search strategy

All publications describing RCTs of home IV antibiotic treatment compared to its administration with in-patient care in CF were identified through detailed computerised searches of The Cochrane Central
Register of Controlled Trials, MEDLINE from 1966 to present (using the search strategy described in the Cochrane Handbook, Section V Appendix 2) and EMBASE 1974 to 1995. Unpublished work was identified through the searching of the abstract books of the three major CF conferences, the International CF conference, the European CF conference and the North American CF conference. Additional RCTs were found from reference lists. All these references to trials

were obtained from the CF trials register held by the editorial base of the Cochrane CF and Genetic Disorders Group, the search strategy for this register is described in detail in the module of the Cochrane CF and Genetic Disorders Group.

The following terms were used in the search of the Group's trials register:
antibiotics
intravenous
home

Handsearching of the abstracts books of all Spanish Conferences on CF and the last European Conference (Stockholm, 2000) was carried out by authors.

Date of the most recent search of the Group's specialised register: April 2002.

METHODS OF THE REVIEW

Three reviewers (Marco T, Gracia de J and Serra C) independently selected the trials to be included in the review. The methodological quality of each trial was assessed by each reviewer. In particular, reviewers examined details of the randomization method, whether the trial was blinded regarding assessment, whether intention to treat analyses were possible from the available data and if the number of patients lost to follow up or subsequently excluded from the study was recorded. Data were independently extracted by each reviewer using a standardised form, adapted from that proposed by the Cochrane CF and Genetic Disorders Group.

For binary outcome measures, data on the number of patients with each outcome event, by allocated treated group, irrespective of compliance and whether or not the patient was later thought to be ineligible or otherwise excluded from treatment or follow-up was sought to allow an intention-to-treat analysis.

For continuous outcomes, we planned to record either mean change from baseline for each group or mean post-treatment/intervention values and standard deviation or standard error for each group. For binary outcomes, we aimed to calculate a pooled estimate of the treatment effect for each outcome across studies, (the odds of an outcome among treatment allocated patients to the corresponding odds among controls). For continuous outcomes we planned to calculate a pooled estimate of treatment effect by calculating the weighted mean difference. Heterogeneity between trial results was going to be tested for using a standard chi-squared test. We planned to perform a sensitivity analysis based on the methodological quality of the studies, excluding quasi-randomized studies. Subanalysis or sensitivity analysis was also to be carried out based on considering different indications for IV antibiotics (exacerbation or elective), type of programme (without paramedical support) and part home versus all home.

Evaluation of quality:

Methodological quality was assessed based on a method described by Schulz (Schulz 1995). The following dimensions of methodological quality: allocation concealment and generation of the randomization sequence was categorised as adequate, unclear or inadequate. Intention-to-treat analysis was categorised as adequate, unclear or exclusions. RCTs were categorised according to whether assessment blinding had been reported or not.

DESCRIPTION OF STUDIES

Summary details of included studies are given in the "Characteristics of included studies" table.

Seven studies were identified by the initial search. One study reporting results from a total of 17 patients met our inclusion criteria and was included in the review (Wolter 1997). It was carried out in two hospitals in Brisbane (Australia). This study provides data from a total of 17 adolescents and adults patients with CF, with a respiratory infective exacerbation by Pseudomonas aeruginosa. No definition criteria are provided for the diagnosis of CF. A respiratory exacerbation was defined as an increase in dyspnoea with or without increased sputum production, fever or a drop in forced expiratory volume in one second (FEV1). All patients had colonisation of their sputum with P. aeruginosa. Those with unstable disease, dwelling outside the city, a history of non compliance, or an inability to learn treatment techniques were excluded. Patients were randomized in blocks of four, by sealed envelope, to home or hospital therapy. After initial randomization, those with recurrent episodes received alternated treatment arms. The

antibiotic therapy for both arms was ceftazidime 2g 12 hourly and tobramycin 4 to 6 mg/kg daily as a single bolus for a minimum of 10 days. All patients received physiotherapy twice daily, plus 20 minutes of aerobic exercise. Patients assigned to home therapy spent two to four days in hospital before discharge and were taught how to prepare and administer their own IV antibiotics. Assessment days were: admission (Day 0), day 10 of therapy and 10 days after cessation of IV therapy and Rx.

Another study (Davis 1990) met the inclusion criteria. It has not yet been published in full and we do not yet have sufficient information to assess the outcomes of this trial. The authors have been contacted to provide this information and we are awaiting their reply. For this reason it is still awaiting assessment. It was a multicenter study which was carried out in New Orleans (USA) and included a total of 78 patients, of all ages. All patients had CF and a respiratory exacerbation by Pseudomonas aeruginosa and received IV antibiotic therapy (tobramycin and ceftazidime). Thirty five patients were randomized to hospital and 43 patients to home therapy after spending two to four days in hospital before discharge.

Non-randomized studies were not considered for inclusion. This resulted in the exclusion of three studies (Donati 1987; Bosworth 1997; Graf 1997). One study comparing different ways of preparing antibiotics, but not between their administration at home versus in hospital, was also excluded (Ramström 2000). See table of excluded studies for details of the reason for exclusion.

Finally, one study (Klettke 1999) is awaiting assessment, to confirm whether it is the same study as the one excluded (Graf 1997).

We are aware of one ongoing study (Wolter 2000) and plan to include the results of this study once they are published, in a future update of this review.

METHODOLOGICAL QUALITY

The study included in this review was a RCT (Wolter 1997). A number of methodological problems were identified: (1) method of allocation concealment was considered adequate; however, as referred by the contacted author, if the same person was randomizing consecutive patients, it was possible to guess by simple observation the last card in each sealed envelope; (2) the researcher participated in the selection of patients and outcome measures assessment, and this was not blinded; (3) after initial randomization, patients were alternatively assigned to home or hospital arms for subsequent episodes of respiratory infections, being all episodes (initial and subsequent) considered independent and treated equally in the analysis; (4) no information is given on time span between episodes to differentiate episodes from recurrences; (5) a response rate of 31% (17/54 patients) was obtained; (6) intention-to-treat analysis was not carried out, but analysis was based on the 17 patients recruited and their 31 admissions. It is possible that original data from the first admission of each patient can be obtained from contacted author and if so re-analysis will carried out in a next update of this review; (7) outcomes were measured only in the short term (21 days after admission);

Because of those limitations only narrative synthesis was attempted at this stage. It is expected that it will be possible to carry out meta analysis in a next update of the review when additional information will be available.

RESULTS

The results are based on the Wolter study (Wolter 1997). Seventeen patients were enrolled and had 31 admissions: nine patients had one admission, five patients had two admissions, one had three, one had four, and one had five. Each admission was considered in the analysis as an independent event. There were 18 hospital admissions and 13 home admissions. Home and hospital patients were similar at baseline regarding gender, age, admission FEV1 and type of IV line. Ages ranged 10 to 41 years (median 22 years).

Summary details of main results are given in the additional table "Description of results". The median duration of treatments was similar for the home arm than the hospital (12 versus 11 days, p=0.20; range 10 to 24 versus 7 to 26). No significant differences were found in time to next admission between both arms, or for doses of tobramycin. Use of home maintenance antibiotics was lower for home treatment (46% versus 71%). Home patients had fewer investigations performed than hospital patients ($p<0.002$) and general activity was higher in the home group.

No significant differences were found between the groups for clinical outcomes. There were significant differences over

time in FEV1 (p=0.006) and FVC (p=0.02) with improvements after treatment in both groups. No significant differences were found between the groups for improvements in body weight and 12 minutes walk test. Sputum weight was not different between the groups. Sputum cultures were not done at follow-up.

One patient had a pneumothorax associated with central line insertion in the hospital arm. There were no deaths and no short-term re-admissions. No events were attributable to the drugs used. Most patients had peripheral IV lines. Three hospital patients had a central line versus none in the home group. No differences were found for complications of IV lines nor for line changes required. There were no significant changes in serial serum creatinine or serial audiometric measurements. A lower proportion of home patients continued on low-dose home maintenance antibiotic until the final assessment day as compared with inpatients (46% versus 71%, p=0.14), and home patients had fewer investigations performed (p=0.002). Time to next admission was not significantly different between home and hospital therapies.

Quality of life, measured by the Chronic Respiratory Disease Questionnaire (CRDQ) were measured with mean score changes from baseline to day 21 being lower for home patients than inpatients (16.5 versus 29.5; p=0.03). There were no significant differences for dyspnoea (p= 0.25), emotional scores (p=0.11), but mean fatigue score change was lower for home patients (3.6 versus 6.8; p=0.04) as were mastery scores (2.6 versus 5.5; p=0.03). Personal, family, sleeping and eating disruptions scores were higher for home than hospital admissions (23.9 versus 18.3; p<0.001) at day 21. Higher scores indicate a better state of well being.

Direct costs were measured by calculating the hospital cost, the cost of antibiotics and equipment used by home therapy, the cost spent on education or home visits or physiotherapy, and travelling costs. Home therapy was cheaper for families: AUS$15.08 (SD AUS$13.48) per day of home therapy versus AUS$23.77 (SD AUS$17.77) per day of hospitalization. The savings to the hospital for home therapy were AUS$2552.00 per a 10 days admission. Indirect costs were not determined because most patients were students or impaired pensioners and did not suffer financially due to loss of income from hospitalization.

DISCUSSION

This review is based only on one study including 17 patients, and some important methodological limitations were identified. Assessment was not blinded but most outcome measures were assessed by objective instruments. A few important outcome measures were not used, such as the culture of sputum to assess remission of lung infection and compliance with other treatment measures or validated instruments of clinical scores. A few patients in the hospital arm did not complete a 10 days-course of treatment. All this makes it difficult to draw any conclusions for practice from this review. Only adults and adolescents were included, so the results cannot be extrapolated to children. This trial did not addressed whether the patients and/or families preferred home or hospital treatment.

A few other studies have been identified comparing home IV antibiotic treatment in CF patients with its whole administration in the hospital but have been excluded because they did not meet one or more inclusion criteria (see table of excluded studies). One multicenter study which met inclusion criteria was excluded because data were not available. Thus, the majority of investigations carried out in this field includes small samples of patients and includes inappropriate designs. The response rate is in general very low which makes it difficult to draw valid conclusions. This might have been the reason why most studies were of a cross-over design and include subsequent episodes of respiratory infection. Nonetheless, it is probable that recurrent episodes are not independent and long term effects attributed to either treatment locations cannot be assessed.

In the light of the available evidence, it can be said that home therapy does not apparently harm patients in the short term since clinical outcomes gave similar results at all points in time used. It is also cheaper than hospital therapy, for families and the hospital. Quality of life measures are especially important in this context. The current evidence shows that, in general, the quality of life seems to be better when the treatment is administered at home. However, those results need to be interpreted with caution, as assessment of dyspnea, fatigue, emotion and mastery gave worse results for home treatment. Two factors may have contributed to this result: fatigue, which could possibly be due to a higher general activity (housework and social duties) and feelings of lower level of control over the disease and its consequences. On the other hand, no validated instruments were used for family, social, sleep and eating disruptions which may have given beneficial results for home therapy.

Finally, more studies are needed with better designs, including more patients, longer follow-up periods (one year and more) and a broad range of outcome measures. Due to the relatively small number of patients with CF, well conducted multicenter studies may shed more light on the current evidence. Cross-over designs might not be the best approach since assessment of long term results, such as prognostic and survival is difficult.

REVIEWER'S CONCLUSIONS

Implications for practice

The current evidence is too limited to draw conclusions for practice. The limited evidence available is in patients commenced on treatment in hospital and suggests that in the short term home therapy is associated with less social disruption and no serious adverse events. The decision to commence home therapy should be based on individual patients and in units with appropriate oupatient resources.

Implications for research

More research is strongly required, ideally a multicenter, properly designed RCTs including sufficient number of patients to increase statistical power, and allowing outcomes assessments in the long term.

ACKNOWLEDGEMENTS

We would like to thank Marta Roqué for assessing the evaluation of quality and analysis, and M. José Martinez for her support in the writing of the current manuscript. We also want to thank contacted authors Drs. Joanne Wolter, Scott H Davis and Wolfgang Greiner for additional information they provided about their studies.

POTENTIAL CONFLICT OF INTEREST

None known

NOTES

Please see related review:

Shepperd S, lliffe S. Hospital-at-home versus in-patient hospital care (Cochrane Review). In: The Cochrane Library, Issue 4, 2001. Oxford: Update Software.

TABLES

Characteristics of included studies

Study	Wolter 1997
Methods	RCT and cross-over open study. Patients were initially randomized in blocks of four by sealed envelopes, to home or hospital therapy. Subjects experiencing recurrent episodes automatically alternated treatment arms after initial randomization.
Participants	17 patients with a mean age of 22 years, with an infective exarcebation of cystic fibrosis.
Interventions	(1) Home therapy: spent two to four days in hospital before discharge and were taught to prepare and administer their own intravenous antibiotics; patients were discharged with medication and equipment for the duration of the proposed course of treatment; home visits were conducted . (2) Control group: whole treatment was administered in the hospital. All patients received the same antibiotic therapy with ceftazidime 2 g 12 hourly and tobramycin 4 to 6 mg/kg daily as a single bolus for a minimum of 10 days in hospital or at home. Patients were randomly allocated to either groups at the first episode. For subsequent episodes they

	were alternatively allocated to home or hospital arm.
Outcomes	(1) Lung function (2) Weight gain (3) Improvement of clinical score (4) Direct costs (5) Indirect costs (6) Hospital days saved from the provision of treatment at home (7) Quality of life (8) Adverses effects of antibiotics (9) Adverses effects of antibiotics (10) Adverses effects to intravenous treatment (11) Compliance with other treatment.
Notes	All episodes, initial or recurrent, were analysed together. The statistical analysis considered recurrent episodes as independent events. Data on first randomized episodes are not currently available.
Allocation concealment	C

RCT: randomized controlled trial

Characteristics of excluded studies

Study	Reason for exclusion
Bosworth 1997	Observational restrospective study comparing a group of patients who undertook intravenous treatment at home with a group of patients treated at the hospital.
Donati 1987	Controlled but not randomized study. Patients selected to either groups (home or hospital) by the distance from home to hospital. Also those meeting inclusion criteria to receive home therapy were allocated to home treatment by their own preference. Characteristics at baseline were similar for home and hospital patients.
Graf 1997	Controlled but not randomized, intraindividual cross-over trial. This was confirmed after contact with author. Fourteen patients were included to receive either intravenous treatment at home or at the hospital.
Ramström 2000	Randomised cross-over trial on the effect of two different ways of preparation of antibiotics in cystic fibrosis patients with indication of home intravenous antibiotic treatment. No comparison was made between the administration of antibiotics at home versus in hospital.

Characteristics of ongoing studies

Study	Wolter 2000
Trial name or title	Randomised controlled trial of home versus hospital intravenous antibiotic therapy in adults with infectious diseases. Brisbane (Australia).
Participants	82 consenting adults with an infection requiring IV antibiotic therapy with asseses suitability for home care (family support and suitable facilities in the home).
Interventions	(1) Intervention group: home intravenous antibiotic treatment . (2) Control group: whole treatment in hospital.
Outcomes	(1) Clinical results of therapy (improvement, failure or readmission in less than 30 days) (2) QOL: Short Form 36 (SF-36) and Perceived Health Competence Scale (PHCS). (3) Adverse effects (4) Hospital costs (daily inpatient charge, DRG, cost of antibiotics and equipment at home, travel costs)
Starting date	1999
Contact	Dr. Ruth Cagney. University Department of Medicine. Master Adult Hospital. South Brisbane,

information	4101.
Notes	In process of publication, once available, data to be included in subsequent update.

IV: intravenous; QOL: quality of life

ADDITIONAL TABLES

Table 01 DESCRIPTION OF RESULTS

Study ID	Participants	Outcomes	Results	Comments
Wolter 1997	Adolescents and adults with an infective exacerbation of CF	(1) Mean duration treatment (2) Lung function (3) Weight gain (kg) (4) Oximetry (%) (5) Sputum weight (g) (6) 12 minutes walk (7) Quality of life (mean scores) (8) Direct costs	(1) Hospital 11.0 days (range 7-26) versus home 12.0 days (range 10-24) (p=0.2). For the outcomes 2 to 6, results are given home vs. Hospital at three time intervals: day 0; day 10; day 21 (post-Rx) (2) FVC (%predicted): day 0 (56 versus 58); day 10 (58 versus 64); day 21 (58 versus 66);p=0.30 FEV1 (% predicted): day 0 (56 versus 39); day 10 (45 versus 50); day 21 (43 versus 51);p=0.27 (3) Day 0 (53.7 versus 52.5); day 10 (54.1 versus 53.4); day 21 (53.9 versus 53.2);p=0.10 (4) Day 0 (93 versus 94); day 10 (94 versus 95); day 21 (94 versus 96);p=0.44 (5) Day 0 (54.7 versus 32.5); day 10 (37.4 versus 19.3); day 21 (29.2 versus 30.6);p=0.09 (6) Day 0 (1254 versus 1163); day 10 (1363 versus 1267); day 21 (1363 versus 1326);p=0.11 (7) Home versus hospital change between day 0 and 21 are given, except for family, personal, sleep and eating disruptions for which only values at day 21 are provided: Dyspnea: 5.9 versus 8.2; p=0.25 Fatigue: 3.6 versus 6.8;	The unit of analysis is the admission. The analysis is based on 17 patients and 31 admissions. Nine patients had one admission, five two admissions, one had three, one had four, and one had five. It is not known whether admissions were different episodes or recurrences.

			p=0.04 Emotional: 4.4 versus 8.6; p=0.11 Mastery: 2.6 versus 5.5; P=0.03 Family disruption: 6.2 versus 4.5; p=0.001 Personal disruption: 5.1 versus 3.8; p=0.004 Sleep disruption: 6.0 versus 4.4; p=0.005 Eating disruption: 6.6 versus 5.9; p=0.007 Total disruption: 23.9 versus 18.3; p<0.001 8) Home vs. hospital: mean (SD) - Cost for families 7 day: $15.08 ($13.48) vs. $23.77 ($17.77). - Savings for hospital by 10 days of home therapy: $2552.00	

REFERENCES

References to studies included in this review

Wolter 1997 {published data only}

Wolter J, Bowler S, Nolan P, McCormack J. Intravenous home therapy: a randomised trial in adult cystic fibrosis patients [abstract]. Australian & New Zealand Journal of Medicine 1995;25:567.

*Wolter JM, Bowler SD, Nolan PJ, McCormack JG. Home intravenous therapy in cystic fibrosis: a propective randomized trial examining clinical, quality of life and cost aspects. European Respiratory Journal 1997;10:896-900.

References to studies excluded from this review

Bosworth 1997

Bosworth DG, Nielson DW. Effectiveness of home versus hospital care in the routine treatment of cystic fibrosis. Pediatric Pulmonology 1997;24:42-7.

Donati 1987

Donati MA, Guenette G, Auerbach H. Prospective controlled study of home and hospital therapy of cystic fibrosis pulmonary disease. Journal of Pediatrics 1987;111:28-33.

Graf 1997

Graf von der Schulenburg JM, Greiner W, Klettke U, Wahn U. Economic aspects in treatment of cystic fibrosis with chronic pulmonary pseudomonas infection. Ambulatory intarvenous therapy in comparison with inpatient treatment [Ökonomische Aspekte der Behandlung zysticher Fibrose mit chronischer pulmonaler Pseudomonasinfektion. Ambulante intravenöse Therapie im Vergleich zur stationären Behandlung]. Medizinische Klinik 1997;92:626-9.

Ramström 2000

Ramström H, Erwander I, Mared L, Kornfält R, Seiving B. Pharmaceutical intervention in the care of cystic fibrosis patients. Journal of Clinical Pharmacy and Therapeutics 2000;25(6):427-34.

References to studies awaiting assessment

Davis 1990

Davis S, Mather F, Tankersly P, Waring W, The Home IV Antibiotic Study Group. A randomized trial of home intravenous antibiotic therapy (HIVAT) in Cystic Fibrosis (CF): Short-Term Safety and efficacy [abstract]. Pediatric Pulmonology 1990;(Suppl 5):207.

*Davis S, Mather F, Waring W, The Home IV Antibiotic Study Group. A randomized trial of home intravenous antibiotic therapy (HIVAT) in Cystic Fibrosis (CF): Short-Term psychological effects [abstract]. Pediatric Pulmonology 1990;(Suppl 5):338.

Klettke 1999

*Klettke U, Maagdorf K, Staab D, Paul K, Wahn U. Ambulatory vs. inpatinent intravenous antibiotic therapy in mucoviscidosis patients - a controlled study. Pneumologie 1999;53:31-36.

Magdorf K, Klettke U, Staab D, Paul K, Wahn U. Home intravenous antibiotic therapy vs. hospital therapy - an alternative for patients with cystic fibrosis? [abstract]. Monatsschrift Fur Kinderheilkunde 1996;144:1047.

References to ongoing studies

Wolter 2000

Dr. Ruth Cagney. University Department of Medicine. Master Adult Hospital. South Brisbane, 4101.. Randomised controlled trial of home versus hospital intravenous antibiotic therapy in adults with infectious diseases. Brisbane (Australia).. Ongoing study. 1999.

Wolter J, Cagney RA, McCormack JG. A randomised trial of home vs hospital intravenous antibiotic therapy in adults with infectious diseases [unpublished].

Additional references

Bosworth 1997

Bosworth DG, Nielson DW. Effectiveness of home versus hospital care in the routine treatment of cystic fibrosis. Pediatric Pneumology 1997;24:42-7.

David 1986

David TJ. Intravenous antibiotics at home in children with cystic fibrosis. Journal of the Royal Society of Medicine 1986;82:130-1.

Davis 1996

Davis PB, Drumm M, Konstan MW. Cystic fibrosis. State of the Art. American Journal of Respiratory and Critical Care Medicine 1996;154:1229-56.

Donati 1987

Donati MA, Guenette G, Auerbach H. Prospective study of home and hospital therapy of cystic fibrosis pulmonary disease. Journal of Pediatrics 1987;111:28-33.

Pond 1994

Pond MN, Newport M, Joanes D, Conway SP. Home versus hospital intravenous antibiotic therapy in the treatment of young adults with cystic fibrosis. European Respiratory Journal 1994;7:1640-4.

Rucker 1974

Rucker RW, Harrison GM. Outpatient intravenous medication in the management of cystic fibrosis. Pediatrics 1974;54:358-60.

Schulz 1995

Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment in controlled trials. Journal of the American Medical Association 1995;273:408-12.

Strandvik 1992

Strandvik B, Hjelte L, Malmborg AS, Widen B. Home intravenous antibiotic treatment of patients with cystic fibrosis. Acta Paediatrica 1992;82:340-4.

** Indicates the major publication for the study*

GRAPHS

This review has no graphs.

COVER SHEET

Title	**Home intravenous antibiotics for cystic fibrosis**
Reviewer(s)	**Marco T, Asensio O, Bosque M, de Gracia J, Serra C**
Contribution of reviewer(s)	**All authors have participated in writing the protocol and the review. Consol Serra, Oscar Asensio and Montse Bosque have participated in the search, and Javier de Gracia, Teresa Marco and Consol Serra in the evaluation of studies and extraction of data.**
Issue protocol first published	2000/1
Issue review first published	2000/4
Date of most recent amendment	25 August 2000
Date of most recent SUBSTANTIVE amendment	07 July 2000
Most recent changes	The Group's trials register was searched in April 2002. Excluded StudiesOne study - Ramström 2000 has been incorporated into the review. Included StudiesAn additional reference [abstract] was added to the existing Wolter 1997 study ID. Studies Awaiting AssessmentAn additional reference [abstract] was added to the existing Klettke 1999 study ID.
Date new studies sought but none found	Information not supplied by reviewer
Date new studies found but not yet included/excluded	Information not supplied by reviewer
Date new studies found and included/excluded	06 November 2002
Date reviewers' conclusions section amended	Information not supplied by reviewer
Contact address	Dr Teresa Marco Pediatrician Department of Pediatrics Corporació Sanitaria Parc Tauli de Sabadell Parc Tauli, s/n Sabadell

08208
SPAIN
tel: +34 937 231010
TMarco@cspt.es
fax: +34 937 160676

Cochrane Library number	CD001917
Editorial group	Cochrane Cystic Fibrosis and Genetic Disorders Group
Editorial group code	HM-CF

SOURCES OF SUPPORT

External sources of support

- Fundacio Marato de TV3 (Barcelona) SPAIN

Internal sources of support

- Corporacio Sanitaria Parc Tauli de Sabadell SPAIN

SYNOPSIS

Home therapy does not harm people with cystic fibrosis in the short term and reduces disruption to their lives to a lesser extent than treatment in hospital

Cystic fibrosis is a serious genetic disorder found in Caucasians that affects cells in the exocrine glands (sweat glands and others). Recurrent lung infections require treatment with intravenous antibiotics for several weeks. Hospital admission is costly and causes disruption to cystic fibrosis sufferers' quality of life. Receiving treatment at home can be done with adequate training and support for sufferers and their carers. The review of trials found home therapy does not generally harm people in the short term but the decision must be looked at on an individual basis. However, the evidence is very limited and more research is strongly needed.

Index Terms

Medical Subject Headings (MeSH)
Adult ; Antibiotics [administration & dosage]; Child ; Cystic Fibrosis [complications]; Home Care Services ; Injections, Intravenous ; Randomized Controlled Trials ; Respiratory Tract Infections [drug therapy] [etiology]; Self Care
Mesh check words: Human