# A randomised cross over trial of nurse versus doctor-led outpatient care in a bronchiectasis clinic

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
25/04/2003		Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/04/2003	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
27/08/2009	Respiratory			

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Diana Bilton

#### Contact details

Cystic Fibrosis and Lung Defence Unit Papworth Hospital NHS Trust Papworth Everard Cambridge United Kingdom CB3 8RE +44 (0)1480 830 541 Ext 4697 drdianabilton@cs.com

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

#### Scientific Title

#### Study objectives

- 1. To assess the feasibility and safety of nurse led outpatient clinics.
- 2. To evaluate the acceptability of nurse led outpatient clinics to patients and GPs.
- 3. To compare the cost effectiveness of a nurse led and doctor led system of care. This is a cross over study of nurse led repeat visits for patients with bronchiectasis, following initial investigation and establishment of a care plan by a consultant physician. The initial phase (9-12 months) is essential to allow training of the nurse practitioner, and introduction of this concept to patients and general practitioners.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration.

#### Study design

Randomised controlled cross-over trial

## Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

**Not Specified** 

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Respiratory tract diseases: Other respiratory tract disease

#### **Interventions**

For the first year of the study patients were randomised to receive either 1 year of nurse practitioner-led care or 1 year of doctor led care. The 2 groups then crossed over to receive the alternate mode of care for a further year. It was important the subjects received each mode of care for a whole year because chronic lung disease is subject to seasonal variation.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Primary outcome was lung function as measured by forced expiratory volume in 1 second (FEV1).

#### Secondary outcome measures

Secondary measures included walking distance, health related quality of life, nurse practitioner autonomy, patient and general practitioner satisfaction with communications and care, patient compliance with treatment and resource group

#### Overall study start date

01/07/1997

#### Completion date

30/11/2000

# **Eligibility**

#### Key inclusion criteria

Patients over 18 years with moderate or severe bronchiectasis confirmed by high resolution computed tomography scans.

## Participant type(s)

**Patient** 

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Target number of participants

80

#### Key exclusion criteria

Not provided at time of registration.

#### Date of first enrolment

01/07/1997

#### Date of final enrolment

30/11/2000

# Locations

#### Countries of recruitment

England

Study participating centre
Cystic Fibrosis and Lung Defence Unit
Cambridge
United Kingdom
CB3 8RE

# Sponsor information

#### Organisation

Department of Health (UK)

#### Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/en/index.htm

#### **ROR**

https://ror.org/03sbpja79

# Funder(s)

## Funder type

Government

#### **Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	HTA monograph	01/04/2002		Yes	No
Results article	results	01/08/2002		Yes	No