ISRCTN77271265 https://doi.org/10.1186/ISRCTN77271265

Randomised trial of outpatient versus inpatient initiation on non-invasive ventilation (NIV) in adults and children with chronic ventilatory failure

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
25/10/2011

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anita K Simonds

Contact details
Respiratory Medicine
Royal Brompton & Harefield NHS Trust
Sydney Street
London
United Kingdom
SW3 6NP
+44 (0)20 7351 8911
a.simonds@rbh.nthames.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0201109246

Study information

Scientific Title

Study objectives
Aim is to investigate whether starting NIV as an outpatient is as effective in terms of physiological improvement, tolerance and compliance, as standard inpatient initiation. We will also determine the cost and staffing implications of this change in clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was received from the local medical ethics committee before trial recruitment began.

Study design
Randomised controlled 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: Chronic ventilatory failure

Interventions
24 patients fulfilling entry criteria will be randomised to outpatient or inpatient initiation of NIV using a block randomisation process to ensure balance for diagnosis and age.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
13/02/2002

Completion date
31/12/2003

Eligibility

Key inclusion criteria
24 patients per year.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
24

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
13/02/2002

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Respiratory Medicine
London

United Kingdom
SW3 6NP

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Royal Brompton and Harefield NHS Trust (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?
Results article	results	01/11/2008		Yes	No