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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2004		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2004	Completed	[X] Results		
Last Edited 25/10/2011	Condition category Respiratory	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number 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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2003

Eligibility

Key inclusion criteria

24 patients per year.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre Respiratory Medicine

London United Kingdom SW3 6NP

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Funder Name

Royal Brompton and Harefield NHS Trust (UK)

Results and Publications

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