

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	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ 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.

Primary study design

Interventional

Study design

Randomised controlled trial

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**

Government

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