ISRCTN51420481 https://doi.org/10.1186/ISRCTN51420481

Medium cost effectiveness of automated non-invasive ventilation outpatient set up vs standard fixed level non-invasive ventilation inpatient set up in obese patients with chronic respiratory disease

Submission date
12/06/2014

Recruitment status
No longer recruiting

Registration date
12/06/2014

Overall study status
Completed

Last Edited
08/11/2022

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Patients with obesity and breathing failure often require a mask overnight to help them breathe. At present, the length of hospital stay for such mask ventilation [Non Invasive Ventilation (NIV)] is between 4.5 and 6 days. There is no evidence to support the clinical or cost effectiveness of setting up mask ventilation on an outpatient basis in the clinic, compared to inpatient set-up on the ward by specialist respiratory nurses, although this is increasingly used as a strategy in smaller units without inpatient facilities. In essence, financial constraints are driving a practice that has no current evidence base in this patient group. Obese patients with long-term respiratory failure have complex physiological changes and often require much higher mask ventilation pressures than other patients needing hospital admission to gain control of their sleep disordered breathing. This will be the first study to test whether outpatient set-up mask ventilation in obese patients with chronic respiratory failure is clinically effective and cost effective at 3 months.

Who can participate?
Stable obese patients attending for management of chronic respiratory failure related to obesity.

What does the study involve?
Patient are randomly allocated to one of two groups: intervention and standard treatment. Intervention group patients are initiated on NIV during an optional outpatient clinic review during which an arterial blood gas measurement (from the wrist) is taken to confirm the presence of long-term respiratory failure. Patients in the standard treatment group are admitted for an inpatient initiation of NIV.

What are the possible benefits and risks of participating?
By taking part in the research, participants are helping shape the future management of patients with the same condition. All of the other research tests are not invasive so there will be no direct risk to participants.

Where is the study run from?
1. St Thomas' Hospital, London, UK (lead site)
2. St James' Hospital, Leeds, UK
3. Royal Brompton Hospital, London, UK
4. Royal Free Hospital, London, UK
5. University Hospital of Grenoble, France
6. University Hospital of Rouen, France

When is the study starting and how long is it expected to run for?
April 2014 to April 2018

Who is funding the study?
Phillips Respironics (UK)

Who is the main contact?
Gill Arbane (Project Coordinator)
gill.arbane@gstt.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Ms Gill Arbane

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
139750

ClinicalTrials.gov number
NCT02342899

Secondary identifying numbers
16392; IRAS 139750

Study information

Scientific Title
Medium cost effectiveness of automated non-invasive ventilation outpatient set up vs standard fixed level non-invasive ventilation inpatient set up in obese patients with chronic respiratory disease: a randomised controlled trial

Acronym
OPIP

Study objectives
The OPIP Trial will be a randomised controlled trial by an international group to evaluate the cost effectiveness on an automated non-invasive ventilation outpatient set up vs. standard fixed level non-invasive ventilation inpatient set up (mask ventilation) for initiation for obese patients with chronic respiratory failure. OPIP will evaluate standard treatment costs and patients health related quality of life and change in a gas exchange.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 10/02/2020:
Approved 27/05/2014, NRES Committee London- Westminster (Bristol REC Centre Level 3, Block B, Whitefriars Lewins Mead, Bristol, BS1 2NT; +44 0117 342 138; nrescommittee.london-westminster@nhs.net), ref: 14/LO/0414

Previous ethics approval:
NRES Committee London, Westminster, 27/05/2014, ref: 13/LO/1362

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Metabolic and endocrine disorders, Respiratory disorders; Subtopic: Metabolic and Endocrine (all Subtopics), Respiratory (all Subtopics); Disease: Metabolic & Endocrine (not diabetes), Respiratory

Interventions
A randomised controlled trial of Outpatient vs Inpatient NIV Set Up, randomised by site, gender and previous mask use, to determine clinical and cost effectiveness of outpatient set up. All patients will keep a record of Health Care Utilisation and be followed up with telephone calls from the research team throughout the trial.

Patients will be seen at baseline, 6 weeks and 3 months, primary outcome measure will be cost effectiveness.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cost effectiveness of standard treatment costs and health related quality of life (SRI and Eq-5D); Timepoint(s): Baseline, 6 weeks and 3 months

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2014

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Obese patients with chronic respiratory failure
2. Age >18 years
3. Chronic hypercapnia (daytime pCO2>6.5kPa)
4. Evidence of sleep disordered breathing on overnight oximetry study (4% oxygen desaturation index>10 events per hour and/or >30% of the total analysis time with an SpO2 <90%)
5. BMI>35kg/m2
6. FEV1/FVC>70%
7. Tolerates NIV>4 hours on first night during initiation of NIV

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size = 82, UK sample size = 62

Total final enrolment
82

Key exclusion criteria
1. Persistent hypercapnic respiratory failure with acidosis (defined as pH <7.30)
2. Severe hypoxic and/or hypercapnic respiratory failure defined as PaO2<7.0kPa and/or PaCO2>9kPa
3. Failure to tolerate NIV during initiation or if required to treat acute decompensation
4. Prior acute hypercapnic respiratory failure requiring intubation
5. Hypercapnic respiratory failure secondary to an identifiable cause other than obesity
6. Unstable coronary artery syndrome
7. Cognitive impairment that would prevent informed consent into the trial and/or inability to comply with the protocol
8. Psychiatric disease necessitating anti-psychotic medication, ongoing treatment for drug or alcohol addiction, persons of no fixed abode post-discharge
9. Patients undergoing renal replacement therapy
10. Patients with co-existent cancer and a prognosis likely to be less than 12-months
11. Critical peripheral vascular disease awaiting re-vascularisation procedure (or claudication distance <100 metres)
12. Stroke with hemiparesis
13. Age <18 years
14. Pregnant

Date of first enrolment
01/07/2014

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
England

France

Switzerland

United Kingdom

Study participating centre
St Thomas's Hospital
London
United Kingdom
SE1 7EH

Study participating centre
St James' Hospital
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Brompton Hospital
London
United Kingdom
SW3 6NP

Study participating centre
Royal Free Hospital
United Kingdom
NW3 2QG

Study participating centre
University Hospital of Grenoble
Grenoble
France
38700

Study participating centre
University Hospital of Rouen
France
76000

Sponsor information

Organisation

Guy's and St. Thomas' NHS Foundation Trust (UK)

Sponsor details
Department of Immunology
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Philips Respironics Inc (UK)

Results and Publications

Publication and dissemination plan
Plan publication in a high-impact peer reviewed journal in April 2019.

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/04/2015		Yes	No
Results article		02/09/2022	08/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No