ISRCTN75718175 https://doi.org/10.1186/ISRCTN75718175

Randomised controlled study of the effect of low flow oxygen on capillary blood gases after acute stroke

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 03/05/2018	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0547130894

Study information

Scientific Title
Randomised controlled study of the effect of low flow oxygen on capillary blood gases after acute stroke

Study objectives
We hypothesise that oxygen supplementation will reduce stroke-induced hyperventilation and normalise blood gases and respiratory rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norwich Local Research Ethics Committee (UK)

Study design
Randomised controlled trial (unblinded)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cardiovascular: Stroke

Interventions
Interventions added as of 18/07/2007:
Patients will be randomised into control and intervention groups by randomly picking up envelopes with predetermined entry to either group. Controls receive routine care without oxygen and the intervention group will receive 2 litres of oxygen per minute via nasal cannula over 24 hours. Pulse oximetry and arterial blood gases will be done on air as baseline. Oxygen will be given to the intervention group continually for the minimum of 24 hours via nasal cannula. Blood gases will be rechecked at the end of the 24-hour period. Pulse oximetry measurements will be recorded throughout the 24-hour period.

Intervention Type

Other

Primary outcome measure
Main outcome measures:
1. Changes in pH at the end of experiment
2. Changes in pCO2 at the end of experiment
3. Changes in respiratory rate at the end of experiment

Other relevant outcome measures:
1. Change in blood pressure
2. Change in pulse oximetry

Secondary outcome measures
Added 18/07/2007:
No secondary outcome measures

Overall study start date
01/06/2003

Completion date
30/04/2011

Eligibility

Key inclusion criteria
Added 18/07/2007:
Patients who are admitted within 24 hours of a presumed vascular stroke (either ischaemic or haemorrhagic) resulting in hospitalisation with significant motor disability (right /left hemiparesis) defined as power 3 out of 5 or less in at least one limb.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
40 (20 into intervention and 20 into control group).

Key exclusion criteria
Added 18/07/2007:
1. History of Chronic Obstructive Pulmonary Disease (COPD) / asthma with a previous history of CO2 retention
2. Presence of acute illness which affects oxygen saturation / delivery or requires oxygen as part of routine management e.g. anaemia (Hb <10), Pulmonary Embolism (PE) or pneumonia

3. Patients whose stroke occurred as a result of condition other than cerebrovascular event (e.g. brain tumour)
4. Comatose patients with Glasgow Coma Scale (GCS) level < 10

Date of first enrolment
01/06/2003

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospital
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospital (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.nnuh.nhs.uk

ROR

https://ror.org/021zm6p18

Funder(s)

Funder type
Government

Funder Name
East Norfolk and Waveney Research Consortium - Norfolk and Norwich University Hospital / Norwich Primary Care 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