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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
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/05/2018	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))

Added 18/07/2007:
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Norfolk and Norwich University Hospital (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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes