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

Submission date	Recruitment status	Prospectively respectively respectively respectively.
30/09/2004	No longer recruiting	[] Protocol
Registration date	Overall study status	[] Statistical analy
30/09/2004	Completed	[_] Results
Last Edited	Condition category	[] Individual partie
03/05/2018	Circulatory System	[] Record updated

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr Phyo Mint

Contact details

Consultant Physician Medicine for the Elderly Norfolk and Norwich University Hospital Colney Lane Norwich United Kingdom **NR4 7UY**

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0547130894

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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 Patients whose stroke occurred as a result of condition other than cerebrovascular event (e.g. brain tumour)
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 c/o Ms Kath Jones Colney Lane Norwich England United Kingdom NR4 7UY + 44 (0)1603 286286 kath.jones@nnuh.nhs.uk

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