Effect of overnight tube feeding on arterial oxygen saturation

Submission date Recruitment status Prospectively registered 30/09/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 30/09/2005 Completed [X] Results Individual participant data **Last Edited** Condition category 11/04/2012 Other

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Dipankar Dutta

Contact details

Elderly Care Department Gloucestershire Royal Hospital Great Western Road Gloucester United Kingdom GL1 3NN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0106153167

Study information

Scientific Title

Study objectives

A randomised study to investigate the effect of overnight tube feeding on arterial oxygen saturation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Not Specified

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

Not Applicable

Interventions

Group 1: feeding on night one Group 2: feeding on night two

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Fall in oxygen saturation of 1% or more

Secondary outcome measures

Not provided at time of registration

Overall study start date

14/10/2004

Completion date

31/10/2005

Eligibility

Key inclusion criteria

32 patients receiving tube feeding:

- 1. Adult patients above the age of 18 years, no upper age limit
- 2. Diagnosis of ischaemic or haemorrhagic stroke within the last 18 weeks
- 3. Patient fed by NG or PEG tube

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

32

Key exclusion criteria

- 1. Patients who are terminally ill
- 2. Patients already on supplemental oxygen for any reason

Date of first enrolment

14/10/2004

Date of final enrolment

31/10/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Elderly Care Department

Gloucester United Kingdom GL1 3NN

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Gloucestershire R&D Consortium (UK), NHS R&D Support Funding

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2004		Yes	No
Results article	results	01/11/2006		Yes	No