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Is looped nasogastric tube feeding more effective than conventional nasogastric tube feeding in dysphagia after acute stroke?

Submission date 05/04/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/04/2006	**Overall study status** Completed	
Last Edited 30/07/2010	**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
9.0

Study information

Scientific Title

Study objectives
Does use of the looped nasogastric tube (LNGT) in dysphagic acute stroke patients result in a greater proportion of nutritional prescription received per patient over a two-week period than conventional nasogastric tube use?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Nottingham Research Ethics Committee 2 on the 22nd August 2006 (ref: 06/Q2404/60).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Please note that this trial has now closed and analysis is underway. The previous anticipated end date for this trial was 01/12/2008.

Interventions:
The intervention group will receive all usual care except that the looped nasogastric feeding tube will be used for feed delivery. Subjects will have the loop component of the LNGT sited as per manufacturers instructions. The loop will be sited by either the research fellow, stroke nurses or ward staff who will have been fully trained in placing the loop. A nasogastric tube (NGT) will be passed and once in place fixed using the loop, thus creating the looped nasogastric

tube. Upon confirmation that the NGT is correctly located, feeding will be commenced on an incremental fashion as per local protocols, which will vary between the centres.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Percentage of nutritional prescription received (amount delivered/amount intended as per dieticians prescription, including all feed and fluids) delivered in the two weeks from allocation or at the point NG feeding is stopped earlier on clinical grounds.

Secondary outcome measures
1. Number of times tube re-sited in two weeks; treatment failure/completed treatment as specified (where treatment failure means any occasion where attempts at nasogastric tube feeding is ceased before normal oral intake is established, and includes multiple failed attempts at passing a tube, use of a percutaneous endoscopic gastrostomy (PEG) (in first two weeks), death or deterioration such that feeding is considered unsafe or unwanted)
2. Mean volume of nasogastric feed delivered in the two weeks from allocation
3. Proportion of patients requiring early PEG insertions
4. The technical efficiency (that is whether the best outcome is being achieved within a given set of resources) of looped nasogastric feeding after stroke compared to ordinary nasogastric tubes will be assessed from an National Health Service (NHS) perspective to see if this new technology offers value for money. An intervention specific outcome will be used to estimate an incremental cost-effectiveness ratio in the form of a cost per change in percentage nutritional prescription received.
5. Change in Demiquet index from baseline to two weeks (weight in kilograms)
6. Tolerability or acceptability of technique by questionnaires to patients, families and nursing staff

Overall study start date
01/06/2006

Completion date
01/05/2008

Eligibility

Key inclusion criteria
Any adult (>18 years of age) with an acute clinically diagnosed stroke as defined by World Health Organisation (WHO) standards; managed on the stroke unit. A clinical decision to attempt nasogastric tube feeding according to usual protocols has been made by the attending clinical team.

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110

Key exclusion criteria
1. Those not consenting to either nasogastric tube (NGT) placement or to entry into the trial
2. Those lacking capacity for whom NG feeding is determined not to be in their best interests
3. Pregnant women
4. Those with contraindications to NG feeding (nasal trauma/malignancies)

Date of first enrolment
01/06/2006

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Senior Lecturer/Geriatrician
Leicester
United Kingdom
LE1 9HN

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research Support and Commercialisation Office
University of Nottingham
University Park

Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research organisation

Funder Name
Royal College of Physicians (UK)

Alternative Name(s)
RCP

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
Dunhill Medical Trust Fellowship (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/08/2007		Yes	No
Results article	results	01/09/2010		Yes	No