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

Submission date 05/04/2006

Recruitment statusNo longer recruiting

ing [X] Protocol

Registration date

Overall study status

Statistical analysis plan

13/04/2006

Completed

[X] Results

Last Edited

Condition category
Circulatory System

Individual participant data

[X] Prospectively registered

30/07/2010

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation

University of Nottingham (UK)

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

Research organisation

Funder Name

Royal College of Physicians (UK)

Alternative Name(s)

Royal College of Physicians of London, King's College of Physicians, 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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