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A study of the clinical application of a fixation device for nasogastric and nasoenteral feeding tubes

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/12/2014	Nutritional, Metabolic, Endocrine	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265006713

Study information

Scientific Title
A study of the clinical application of a fixation device for nasogastric and nasoenteral feeding tubes

Study objectives
1. Is nasogastric tube fixation acceptable in this country to patients, their relatives, nursing and medical staff?
2. Does nasogastric tube fixation improve nutrient delivery?
3. Does nasogastric tube fixation reduce the number of invasive procedures undergone by patients (nasogastric tube insertions, gastrostomy placement referrals, parenteral feeding referrals)?
4. Is there any difference in clinical outcome between patients that have nasogastric tube fixation and those that do not?

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine

Interventions
Any patient that requires nasogastric tube feeding that has had the tube removed or displaced accidentally on one occasion will be referred to the investigators. The patients will be randomised by assigning alternate patients to current practice (repeated attempts at nasogastric tube placement, referral for alternative routes of feeding, etc) or to nasogastric tube placement with tape fixation. Only patients in this arm of the study will require consent (specimen form attached) and an information sheet will be left with the patient. In the event of the patient being unable to consent, the procedure will be discussed with the next of kin from

whom consent will be obtained. Outcomes will be recorded on an observation sheet attached to the patient's file. Competent patients will be questioned during the trial and after removal of the tube to determine acceptability. The trial will be terminated.

Intervention Type
Device

Phase
Not Specified

Primary outcome measure
1. Duration of nasogastric feeding
2. Number of nasogastric tube insertions attempted
3. Proportion of target feed volume delivered
4. Amount of time without tube in place
5. Acceptability of technique to patients, their relatives and staff
6. Number of referrals made for alternative feeding routes
7. Time to resumption of oral feeding
8. Patient discomfort or nasal discharge

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2004

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment

01/01/2004

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

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
Hospital/treatment centre

Funder Name
University Hospital Birmingham NHS 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