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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr JM Woodward

#### Contact details

Anatomy Selly Oak Hospital Birmingham United Kingdom B29 6JD

# Additional identifiers

# Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

- 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

# Key secondary outcome(s))

Not provided at time of registration

## Completion date

01/01/2007

# **Eligibility**

## Key inclusion criteria

Not provided at time of registration

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

## Age group

**Not Specified** 

## Sex

**Not Specified** 

# 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

United Kingdom

England

# Study participating centre

# Selly Oak Hospital

Birmingham United Kingdom B29 6JD

# Sponsor information

# Organisation

Department of Health

# Funder(s)

## Funder type

Hospital/treatment centre

## **Funder Name**

University Hospital Birmingham NHS Trust (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration