

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

**Submission date**  
30/09/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
30/09/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**  
12/12/2014

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

## 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  
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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