

# A multicentre international randomised trial to evaluate percutaneous endoscopic gastrostomy (PEG) and nasogastric (NG) tube feeding in patients admitted to hospital with a recent stroke

<b>Submission date</b> 20/03/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/03/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/07/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
HTA 96/29/01

# Study information

## Scientific Title

## Acronym

FOOD

## Study objectives

FOOD is an international, randomised trial involving a total of at least 4,000 patients which aims to address the following issues:

1. In stroke patients who cannot swallow, does feeding via a Percutaneous Endoscopic Gastrostomy (PEG) tube improve survival free of severe disability compared with that via a nasal gastric (NG) tube? (500 patients in each arm)
2. In patients who cannot swallow within the first week of admission, is immediate initiation of feeding via either a PEG or NG tube (rather than simply hydrating the patient to see if dysphagia will rapidly resolve) associated with improved outcomes? (500 patients in each arm)

We will assess the impact of particular feeding regimes on lower complication rates, mortality, improved quality of life amongst survivors and resource use. Using the same trial infrastructure we will also address a third related question: in patients who can swallow, does routine addition of oral nutritional supplements to the normal hospital diet improve patients' outcomes? (1000 patients in each arm). No additional resources are requested to address this third question. We believe that the inclusion of a trial addressing this last question will facilitate the more rapid completion of the tube feeding arms.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/962901>

On 16/01/2008 the start and end date of this trial were changed from 1/11/1996 and 31/07/2003 to 01/02/1999 and 31/12/2004, respectively.

## 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

Stroke

## Interventions

**Interventions:**

Trial 1: Normal hospital diet versus normal hospital diet plus oral supplements (comprising 120 ml containing 1.5 kcal/ml three times a day)

Trial 2: Immediate tube feeding (NG or PEG) versus delay tube feeding for at least a week and hydrate using parenteral fluids

Trial 3: NG versus PEG

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Survival without disability, mortality

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/12/2004

**Eligibility****Key inclusion criteria**

Any patient admitted to hospital with a stroke (excluding those with subarachnoid haemorrhage) within a week of onset, in whom the randomising clinician is substantially uncertain about the best feeding policy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

All

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/02/1999

**Date of final enrolment**

31/12/2004

# Locations

## Countries of recruitment

United Kingdom

Scotland

Argentina

Australia

Belgium

Brazil

Canada

Czech Republic

Denmark

Hong Kong

India

Ireland

Italy

New Zealand

Poland

Portugal

Singapore

Türkiye

## Study participating centre

**FOOD Trial Co-ordinating Centre**

Edinburgh

United Kingdom

EH4 2XU

## Sponsor information

## Organisation

Department of Health (UK)

## ROR

<https://ror.org/03sbpja79>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

### 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?
<a href="#">Results article</a>	results	01/02/2005		Yes	No
<a href="#">Results article</a>	results	01/02/2005		Yes	No
<a href="#">Results article</a>	results	01/01/2006		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes