

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

Submission date 20/03/2002	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/03/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/07/2014	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr MS Dennis

Contact details
FOOD Trial Co-ordinating Centre
Neurosciences Trials Unit
Western General Hospital
Edinburgh
United Kingdom
EH4 2XU
+44 (0)131 5372939
MSD@skull.dcn.ed.ac.uk

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

Primary study design

Interventional

Study design

Randomised controlled trial

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?
Results article	results	01/02/2005		Yes	No
Results article	results	01/02/2005		Yes	No
Results article	results	01/01/2006		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes