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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/03/2002	**Overall study status** Completed	
Last Edited 09/07/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.dcn.ed.ac.uk/food/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details provided in the Interventions field to request a patient information sheet

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 measure
Survival without disability, mortality

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/1999

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

Age group
Not Specified

Sex
Both

Target number of participants
4,023

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
Argentina

Australia

Belgium

Brazil

Canada

Czech Republic

Denmark

Hong Kong

India

Ireland

Italy

New Zealand

Poland

Portugal

Scotland

Singapore

Türkiye

United Kingdom

Study participating centre
FOOD Trial Co-ordinating Centre
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Sponsor information

Organisation
Department of Health (UK)

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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

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