Does intensive feeding improve nutritional status and outcome in acutely ill older inpatients?

Submission date Recruitment status Prospectively registered 23/01/2004 No longer recruiting [] Protocol Statistical analysis plan Registration date Overall study status 23/01/2004 Completed [X] Results [] Individual participant data Last Edited Condition category 12/01/2010 Other

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Gary Frost

Contact details

Hammersmith Hospital NHS Trust
Department of Nutrition and Dietetics
Hammersmith Hospitals NHS Trust
Ducane Road
London
United Kingdom
W12 0HS
+44 (0)20 8383 3948
Gfrost@hhnt.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers RDC00891

Study information

Scientific Title

Study objectives

Malnutrition has been estimated to cost the NHS £220 million a year because malnourished patients have longer hospital stays and increased morbidity. Malnutrition is particularly common in the elderly. Most intervention studies in this group have used liquid supplements but the results have been disappointing; even under surveillance, ill older patients often do not take enough supplement to improve their nutritional status. In routine clinical practice the situation is even worse because poor nutrition is often not recognised and compliance with supplements is even lower. Another approach is needed. This study examines whether health care assistants trained to provide support with all aspects of feeding can make a significant impact on nutritional intake and whether this improves outcome. The study is designed to determine: Does feeding support increase nutritional intake, lead to measurable changes in nutritional status (body mass index, arm circumference, serum albumin) and lead to improved outcome (infection rate, Barthel score, length of stay, readmission rate)?

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)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Acute illness

Interventions

- 1. Feeding support from health care assistants trained to provide support with all aspects of feeding
- 2. Standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The study is designed to see whether feeding support improves the nutritional status of patients to an extent it will have a positive day to day effect on function, the time patients require to become medically fit for discharge and length of stay.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/1997

Completion date

01/06/2000

Eligibility

Key inclusion criteria

All patients over 65 admitted acutely to Medicine for the Elderly wards. Sample is estimate to be 750 people in each group.

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

1500

Key exclusion criteria

- 1. Patients unable to take food orally (e.g. unconscious, severe dysphagia)
- 2. Not expected to survive the current admission
- 3. Patients with a body mass index (BMI) greater or equal to 25

Date of first enrolment

01/12/1997

Date of final enrolment

01/06/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Hammersmith Hospital NHS Trust
London
United Kingdom
W12 0HS

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health 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.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (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	01/02/2004		Yes	No