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Nutritional supplementation and length of stay: a controlled trial of nutritional supplementation in a mixed acute hospital setting

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 11/01/2010	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RDC00898

Study information

Scientific Title

Study objectives
Loss of weight and low body weight expressed as a function of height are both common among patients admitted to hospital. A pilot study has shown that about 30% of patients admitted as emergencies to the Royal London Hospital have biochemically demonstrable B vitamin deficiencies. Several studies have demonstrated the relationship between length of hospital stay, morbidity, mortality and such indices of nutritional status, but it is unclear to what extent this relationship is causal. The principal purpose of this study is to examine the effect of two strategic nutritional interventions in a large number of non-elective admissions to the Royal London Hospital on length of stay and mortality. We propose a randomized placebo controlled trial of early dietary supplementation with a palatable liquid oral sip feed and/or water soluble vitamins. In this study we have the opportunity further to document nutritional status among such patients and to develop techniques for rapid determination of water soluble vitamin status.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo 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
Other symptoms and general pathology

Interventions
1. Palatable liquid oral sip feed with vitamin supplements
2. Placebo (palatable liquid oral sip feed only)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. It is expected that a significant incidence of biochemical water soluble vitamin deficiency will be detected among the patients admitted via accident and emergency and that HPLC of single blood samples, will provide a reliable method for assay, and prove much more rapid and convenient than the established enzymatic methods of routine screening.
2. The incident of protein/energy malnutrition detected by anthropometric assessment is expected to approximate 40% in the study group of patients.
3. Previous studies suggest that we might expect a reduction of length of stay as a result of feed supplementation of undernourished inpatients. We might also see reductions in mortality in this group.
4. We might detect a reduction in length of stay and mortality as a result of water soluble vitamin supplementation, either in the study population as a whole, or within subgroups identified in the course of the study.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/1997

Completion date
01/09/1999

Eligibility

Key inclusion criteria
1. Patients admitted acutely to general medicine, general surgery and orthopaedics.
2. Patients with a body mass index <22 within the above sample, will be randomized to oral sipfeed or placebo feed, independent of whether they are receiving vitamin supplements.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria

1. Planned admission to medical or orthopaedic wards or to wards other than those 15 taking part in the study.
2. Less than 18 years
3. Mental illness
4. Admission for only 2 days

Date of first enrolment
01/09/1997

Date of final enrolment
01/09/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Bartholomew's & Royal London School of Medicine & Dentistry
London
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E1 1BB

Sponsor information

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

Sponsor details
The Department of Health
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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	01/12/2001		Yes	No