

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/01/2010	Condition category Signs and Symptoms	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

United Kingdom

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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SW1A 2NL

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Sponsor type

Government

Website

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