Preoperative oral carbohydrate drink versus placebo: a pilot study of the role of preoperative oral carbohydrate loading in the outcome of short stay and day surgery

Submission date	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	[] Individual participant data
14/03/2014	Surgery	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N0436118158

Study information

Scientific Title

Study objectives

We aim to test the hypothesis that preoperative oral carbohydrate drink has beneficial effects on fatigue and well-being after surgery as well as on insulin resistance, stress response and immune function.

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Surgery

Interventions

A. Carbohydrate drink

B. Placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

oral carbohydrate

Primary outcome(s)

Outcome measures are to compare the effects of preoperative oral carbohydrate drink versus placebo, primarily on well-being and fatigue in subjects undergoing laparoscopic cholecystectomy.

Key secondary outcome(s))

Secondary outcomes are to compare the effects on stress response.

Completion date

01/08/2006

Eligibility

Key inclusion criteria

Subjects will be recruited from patients due to undergo a laparoscopic cholecystectomy under the care of two consultant surgeons at Wharfedale General Hospital. The study will be explained to those patients suitable for inclusion.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/02/2002

Date of final enrolment

01/08/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Department of Surgery

Leeds United Kingdom LS1 3EX

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration