ISRCTN65541943 https://doi.org/10.1186/ISRCTN65541943

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

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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.

Secondary outcome measures
Secondary outcomes are to compare the effects on stress response.

Overall study start date
01/02/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Department of Surgery
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (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