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Reduction of surgical stress by prevention of perioperative starvation

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 28/03/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S Lewis

Contact details
level 09
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0185146353

Study information

Scientific Title

Study objectives
Does feeding surgical patients improve intestinal permeability and insulin resistance?
The purpose of this study is to examine the effect of maintaining patients nutritional intake in the pre and postoperative period on insulin resistance, nitrogen turnover and intestinal permeability.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery

Interventions
The day before the operation study patients will be encouraged to take clear liquid dietary supplements during the day before their operation and on the day of their operation. Patients in group A will receive a placebo supplement of flavoured water. Patients in groups B and C will receive Fortisip. The amount of supplements will be measured to meet the patients calculated daily energy requirement. On the operative day patients will take 200ml of supplement drink at 8am then another 200ml 4 hours before their operations. In the postoperative period patient will be encouraged to take the liquid supplements as tolerated from the period immediately after their operation until normal diet is resumed. Patients in groups A and B will receive placebo supplement drinks whilst those in group C will receive Fortijuice. Insulin resistance will be measured using the HOMA method and by using a short insulin tolerance test. Intestinal permeability will be measured using a duel sugar test.

Intervention Type

Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
12/09/2002

Completion date
09/02/2008

Eligibility

Key inclusion criteria
60 participants in total - 40 experimental group, 20 control.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
<18 years, diabetic, pregnant or lactating, receiving tube delivered nutrition, participating in another study.

Date of first enrolment
12/09/2002

Date of final enrolment
09/02/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
level 09
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health

Sponsor details
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.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Plymouth Hospitals NHS Trust

Funder Name
NHS R&D Support Funding

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	01/06/2010		Yes	No