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Reduction of surgical stress by prevention of perioperative starvation

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
09/02/2008

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

Study participating centre
level 09
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Plymouth Hospitals NHS Trust

Funder Name
NHS R&D Support Funding

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes