ISRCTN89225485 https://doi.org/10.1186/ISRCTN89225485

# 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

**Contact name**
Dr S Lewis

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

## 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

### Primary study design
Interventional

### Study design
Randomised controlled trial

### 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 |