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SuperStarch Study

Submission date	Recruitment status	[X] Prospectively registered
16/04/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/06/2015	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2023	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Having a surgical operation can be very stressful for the body. It lowers a patient's immune system and disrupts their metabolism for a number of weeks or even months after surgery. These factors can increase the likelihood of complications following surgery, such as getting an infection or developing insulin resistance. Insulin resistance, which occurs in type 2 diabetes, is when the body doesn't produce enough insulin to function properly, or the body's cells stop reacting to insulin. The development of insulin resistance after surgery is very common, and is linked to an increase in disease and death. It has been shown that having a sugar-based carbohydrate drink before surgery can prevent the development of insulin resistance. As a result, patients are usually given a carbohydrate drink to have the night before surgery, and on the morning of surgery, as part of the Enhanced Recovery Programme (ERP) used in many hospitals. The aim of this study is to test an alternative starch drink called Generation UCAN, which does not contain sugar. Generation UCAN is popular as an exercise and sports drink. In this study, patients having bowel surgery are given either Generation UCAN or the standard sugar-based drink PreLoad® before their operation. The research team will then see if there is a difference in insulin resistance and stress response to surgery in patients who drank either PreLoad® or Generation UCAN before their operation.

Who can participate?
Adults having a laparoscopic bowel resection operation.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (control group) are given the standard pre-operative carbohydrate drink Preload®. Those in group 2 (intervention group) are given the new pre-operative starch drink Generation UCAN. All participants receive the same care according to the standard ERP. Blood samples are taken before and after surgery along with routine medical assessments and questionnaires. Follow up continues until 7 days after surgery.

What are the possible benefits and risks of participating?
The only change to patient care in this study will be the exchange of the standard pre-operative carbohydrate drink for a new one in the treatment group. All other aspects of the patient's care will remain the same.

Where is the study run from?
East Lancashire Healthcare Trust (UK)

When is the study starting and how long is it expected to run for?
August 2015 to September 2023

Who is funding the study?
East Lancashire Healthcare Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Study information

Scientific Title
Effect of a modified starch compared to standard maltodextrin on post-operative insulin resistance when given pre-operatively for laparoscopic colorectal surgery as part of an enhanced recovery program: a pilot RCT (SuperStarch Study)

Study objectives
1. Does the use of a modified, long-acting starch before surgery, the first dose taken the night before and the second up to 2 hours before surgery, reduce the development of insulin resistance post-operatively when given as part of an Enhanced Recovery Protocol?
1.1. Primary null hypothesis: There is no difference in postoperative insulin resistance between patients who drink Preload® compared to those drinking Generation UCAN pre-operatively.
1.2. Primary alternative hypothesis: There is a difference in postoperative insulin resistance between patients who drink Preload® compared to those drinking Generation UCAN pre-operatively.
2. Does the use of a modified, long-acting starch before surgery, the first dose taken the night

before and the second up to 2 hours before surgery, attenuate the post-operative stress response and show an improved recovery profile (i.e. reduced incidence of post-operative nausea and vomiting, decreased fatigue and decreased thirst and hunger?) when given as part of an Enhanced Recovery Protocol?
2.1. Secondary null hypotheses: There is no difference in postoperative stress response or in recovery profile between patients who drink Preload® compared to those drinking Generation UCAN pre-operatively.
2.2. Secondary alternative hypotheses: There is a difference in postoperative stress response or in recovery profile between patients who drink Preload® compared to those drinking Generation UCAN pre-operatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Centre of Research Ethics Committees, 26/06/2015, ref: 15/NW/0511

Study design
Randomised controlled unblinded parallel study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-operative insulin resistance

Interventions
Participants are allocated to one of two groups:
1. Group one (control) receives the current pre-operative carbohydrate solution, Preload® (a maltodextrin solution). The Preload® group will follow the standard enhanced recovery protocol (ERP) and ingest two 50g sachets in 800ml water the evening before surgery (providing 95g of carbohydrate) and one sachet (providing 47.5g of carbohydrate) in 400ml water up to 2 hours before surgery. All other aspects of patient care will be standardised as per our ERP.
2. Group two (intervention) receives Generation UCAN (a hydrothermally modified starch solution). This group will ingest 800ml water the night before surgery and 56.55g of flavoured Generation UCAN (providing 47.5g of carbohydrate) in 400ml water up to 2 hours before surgery. All other aspects of patient care will be standardised as per our ERP.

Intervention Type
Supplement

Primary outcome(s)
Change in insulin resistance from baseline on postoperative day 1 (POD 1) measured by Homeostasis Model Assessment (HOMA), which utilises serial fasting blood glucose and insulin measurements.

Key secondary outcome(s))

1. Change in insulin resistance from baseline on POD 2 and POD 3 measured using HOMA
2. Stress response following surgery, measured by sampling cortisol levels preoperatively, at the end of surgery, and at 24 hours post-operatively and the inflammatory response measured by CRP levels pre-operatively, and on POD 1,2 and 3.
3. Ultrasound measurement of gastric volume pre-operatively
4. Recovery profile including:
4.1. PQRS score measured pre-operatively, at 2 hours after surgery, POD 3 and POD 7.
4.2. Muscle strength measured using a grip strength dynamometer pre-operatively, twice daily (morning and afternoon) on POD 1, 2 and 3, and then once daily on alternate days thereafter until discharge (the patient's dominant hand will be used for this measurement, and the best out of three consecutive strengths will be used with mean values analysed).
4.3. Time to surgical fitness for discharge measured in hours (date and time of fitness for surgical discharge is recorded in the ERP database). Morbidity measured using the POMS score on POD 2 and 5.
4.4. PONV VAS score on POD 1.
5. Sensations of thirst & hunger Visual Analogue Scale (VAS) score immediately pre-operatively and on POD 1.
6. Adverse events i.e. aspiration and hypo- or hyperglycaemia (these are the only relevant safety assessments for these interventions) will be assessed on the operative day for the former & up to the end of POD 1 for the latter.
7. Cost analysis: difference in cost between doses of Pre-Load & Generation UCAN and costs of respective hospital and critical care lengths of stay.

Completion date
01/09/2023

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Patients >18 years
2. Laparoscopic colorectal resection
3. Included in Enhanced Recovery Protocol
4. American Society of Anesthesiologists (ASA) Physical Status classification 1-3
5. Able to give consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Non-English speaker
2. Pregnancy
3. Diagnosed diabetes mellitus (diet, drug or insulin controlled).
4. Diagnosed impaired glucose tolerance (fasting glucose in POAC >5.5 mmol/l and/or HbA1C>5.7%)
5. Decreased gastrointestinal motility (from medication or disease) or predisposition to reflux
6. Diagnosis of inflammatory bowel disease
7. Allergy to either preoperative carbohydrate drink

Date of first enrolment
01/08/2022

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation

East Lancashire Healthcare Trust

ROR
https://ror.org/002pa9318

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
East Lancashire Healthcare Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file		17/04/2015	23/08/2022	No	No