

Feasibility and metabolic effects of carbohydrate loading in patients with fragility hip fracture - a randomised double blind pilot study

Submission date 04/07/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/07/2014	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 12/08/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

16941

Study information

Scientific Title

Feasibility and metabolic effects of carbohydrate loading in patients with fragility hip fracture - a randomised double blind pilot study

Acronym

Pre-operative Nutrition In Neck of femur Trial (POINT)

Study objectives

Hip fracture is a common injury affecting predominantly old people. The outcome for patients is often poor with a high mortality following operation, and worsening of mobility and function when compared with that before the injury. It has long been recognized that trauma due to surgery or accident is associated with changes in the way muscles use fuels such as sugar (glucose). These changes come on soon after injury and persist for some time and may have harmful effects on recovery and muscle strength. We also know that poor muscle function is a predictor of poor outcome in the days and months following hip fracture. Researchers in the field of elective surgery have found that providing patients with special carbohydrate drinks before their operation can improve muscle sugar use and have beneficial effects in the postoperative period. However, due to the nature of hip fracture, which is operated on urgently, and in a frail population who are often in pain, providing preoperative drinks may be difficult. The muscle of older people behaves differently to that of younger people so we don't know whether these drinks will have the same effect. Potentially, if we can find out what effect these drinks have on the way muscles behave; this may provide avenues of future research into the optimal way to enhance muscle function following hip fracture. To do this, we wish to study a group of hip fracture patients. We wish to find out what happens to the way their bodies deal with sugar if they have these drinks or if they have normal care without the drinks. We would do this by simple blood tests, and by taking some small tissue samples from leg muscles before and after their operation. Part of the study will also be looking at the practical issues around providing these sorts of drinks to this patient group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East Midlands - Nottingham 1 Research Ethics Committee, 15/07/2013, ref: 13/EM/0214

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Not specified, Prevention

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Enhancement of recovery following hip fracture surgery

Interventions

Pre-op carbohydrate drink, Nutricia Pre-op(r)

400 ml night before surgery

400 ml morning of surgery (up to 2 hours pre-op)

Follow Up Length: 1 month(s); Study Entry: Single Randomisation only

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Oral glucose tolerance test; Timepoint(s): Day 1 post operation

Key secondary outcome(s)

1. Glucose homeostasis - blood glucose; Timepoint(s): Blood glucose prior to induction of anaesthesia
2. Blood glucose on day 1; Glucose homeostasis - insulin; Timepoint(s): Insulin concentration - prior to induction of anaesthesia, Insulin concentration - day 1 post op
3. Length of acute hospital stay; Timepoint(s): Hospital discharge
4. Mobility - Cumulated ambulation score; Timepoint(s): Days 1-3 post-op
5. Muscle metabolism - muscle biopsy, contralateral leg; Timepoint(s): Prior to induction of anaesthesia At end of surgery
Day 1
6. Nausea and vomiting; Timepoint(s): Prior to induction of anaesthesia Day 1 post-operation

Completion date

31/08/2015

Eligibility

Key inclusion criteria

1. Patients presenting through accident and emergency with a fragility neck of femur fracture requiring hemiarthroplasty
2. Aged 70 or over
3. Patients able to provide fully informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Patients who are confused or unable to give their own consent
2. Patient known to suffer with diabetes (either type 1 or type 2)

3. Patients with current infections
4. Ongoing participation in another clinical trial
5. Multiple injuries requiring operative management
6. Previous intolerance to carbohydrate drinks

Date of first enrolment

01/07/2014

Date of final enrolment

31/08/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Queens Medical Centre

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Research organisation

Funder Name

British Journal of Anaesthesia (UK)

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?
Protocol article	protocol	04/12/2014		Yes	No
HRA research summary			28/06/2023	No	No