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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	✓ Retrospectively registered ✓ Protocol added ? SAP not yet added ? Results not yet added and study completed for more than 2 years ? Raw data not yet added ✓ Study completed
Registration date 04/07/2014	**Overall study status** Completed	
Last Edited 12/08/2020	**Condition category** Musculoskeletal Diseases	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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 hypothesis
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

Study design
Randomised; Interventional; Design type: Not specified, Prevention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/07/2014

Overall study end date
31/08/2015

Eligibility

Participant 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

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30; Description: Allow for 3 drop outs per group (20% drop out)

Participant 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

Recruitment start date
01/07/2014

Recruitment end date
31/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research Innovation Services
Kings Meadow Campus
Lenton Lane
Nottingham
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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research organisation

Funder Name
British Journal of Anaesthesia (UK)

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