ISRCTN72860921 https://doi.org/10.1186/ISRCTN72860921

Body swelling after surgery: the influence of poor fluid intake, inflammation and the choice of infusion fluid

Submission date
04/05/2014

Recruitment status
No longer recruiting

Registration date
12/06/2014

Overall study status
Completed

Last Edited
07/02/2018

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Body swelling (a buildup of fluid under the skin) often happens after surgery. The aim of this trial is to investigate the reasons to why it happens. The infusion fluids used in the surgery (e.g. resuscitating fluids), the amount of fluid taken by the patient before the surgery, whether the patient suffers from an inflammatory disease and surgical stress (how the body responds to the surgery) are all possible factors that may influence the amount of swelling that occurs after an operation.

Who can participate?
Adult patients (aged at least 18 years), scheduled for surgery that will last for longer than 30 minutes.

What does the study involve?
Urine samples are taken from the patients before, during and after surgery. A blood sample will also be taken the morning after the operation. Patients will be receive either a crystalloid or a colloid infusion fluid during the surgery and be weighted daily until they leave the hospital. Any complications will be recorded.

What are the possible benefits and risks of participating?
The researchers do not believe that there are any benefits or medical risk involved. There may be pain involved when the blood sample is taken.

Where is the study run from?
Södertälje Hospital, Sweden

When is the study starting and how long is it expected to run for?
June 2012 to September 2015

Who is funding the study?
Stockholm County Council (Sweden)

Who is the main contact?
Professor Robert Hahn
r.hahn@telia.com

Contact information

Type(s)
Scientific

Contact name
Prof Robert Hahn

Contact details
Research Unit, House 18
Södertälje Hospital
Södertälje
Sweden
152 86
+46 (0) 855024670
r.hahn@telia.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2011/657-31/3

Study information

Scientific Title
Mechanisms of oedema after general surgery; a randomized clinical trial of the choice of fluid and the influences of preoperative dehydration, inflammation and surgical stress

Acronym
MPO (Mechanisms of Postoperative Oedema)

Study objectives
That the increase in body weight after surgery can be related to certain preoperative factors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee of Stockholm, 29/06/2011, ref. 2011/657-31/3

Study design
Open randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://roberthahn.se/Oedema.pdf

Health condition(s) or problem(s) studied
General surgery

Interventions
Randomization between using a colloid or a crystalloid fluid for plasma volume support during the surgery. Blood and urine sampling. Recording of postoperative complications according to a prospective survey.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Increase in body weight from before up to the morning after surgery

Secondary outcome measures
1. Dehydration as evaluated by urine samples before surgery
2. Stress and inflammation as detected by serum cortisol and CRP in the morning after the surgery was performed

Overall study start date
01/06/2012

Completion date
30/09/2015

Eligibility

Key inclusion criteria

Adult patients (age >18 years) scheduled for surgery in general anaesthesia lasting for > 30 minutes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Endocrinological disease (such as diabetes)
2. Kidney disease
3. Dementia
4. Heart disease that affects physical performance
5. Difficulty understanding the Swedish language

Date of first enrolment
01/06/2012

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Research Unit, House 18
Södertälje
Sweden
152 86

Sponsor information

Organisation
Stockholm County Council (Sweden)

Sponsor details
c/o Lena Olsén
Hantverkargatan 45
Box 22550
Stockholm
Sweden
10422

Sponsor type
Government

Website
http://www.forskningsstod.sll.se

ROR
https://ror.org/02zrae794

Funder(s)

Funder type
Government

Funder Name
Stockholm County Council (Sweden), grant 20100211

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?
Results article	results	01/04/2017		Yes	No