

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	☐ Prospectively registered ☐ Protocol
Registration date 12/06/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/02/2018	Condition category Surgery	☐ 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/02zrae794>

Funder(s)

Funder type

Government

Funder Name

Stockholm County Council (Sweden), grant 20100211

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	01/04/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes