

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

<b>Submission date</b> 04/05/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/06/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/02/2018	<b>Condition category</b> Surgery	<input type="checkbox"/> 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

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## 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?
<a href="#">Results article</a>	results	01/04/2017		Yes	No