The KIdney during surgery for Hip Fracture repair in elderly patients: possible injury due to poor fluid intake and the choice of infusion fluid during the surgery

| Submission date | Recruitment status Stopped | [X] Prospectively registered | | |
|-------------------|---------------------------------------------------------|------------------------------|--|--|
| 04/05/2014 | | ∐ Protocol | | |
| Registration date | Overall study status Stopped Condition category Surgery | Statistical analysis plan | | |
| 12/06/2014 | | Results | | |
| Last Edited | | Individual participant data | | |
| 23/02/2023 | | Record updated in last year | | |

Plain English summary of protocol

Background and study aims

Acute kidney injury, where the kidneys suddenly become unable to function properly, is a serious complication that can occur during hip fracture surgery in the elderly. This could be due to a number of factors, and this study aims to see whether it may be due to poor fluid intake by the patient (preoperative dehydration) and the choice of infusion fluid (crystalloid or hyperoncotic colloid) used during the operation.

Who can participate?

Adults aged between 70-90 years with a hip fracture and scheduled for surgery.

What does the study involve?

Each patient is randomly chosen to receive either crystalloid or hyperoncotic colloid at the start of the operation. Urine and blood samples will also be taken three times during the course of the day of the surgery.

What are the possible benefits and risks of participating?

All patients will benefit from having their blood circulation monitored using a non-invasive apparatus called the Nexfin. Hyperoncotic colloid can cause fluid to collect in the lungs of susceptible patients, but this is minimized by giving only a small amount of the fluid and also by doing so at the point when the anaesthesia is given; this causes the blood vessels to widen (vasodilation)

Where is the study run from? Södertälje Hospital (Sweden)

When is study starting and how long is it expected to run for? September 2014 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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Kidney injury during hip fracture surgery: a randomized study between crystalloid and colloid fluid and the influence of preoperative dehydration

Acronym

KIHF

Study objectives

Kidney injury that develops during acute hip fracture surgery can be related to preoperative dehydration and/or to the use of albumin 20% for plasma volume support

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethics Committee of Stockholm, 02/04/2014, ref. 2014/497-31/4

Study design

Randomized double-blinded 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/PatientinfoAlb.pdf

Health condition(s) or problem(s) studied

Hip fracture surgery

Interventions

Patients are randomized to receive either 100 ml of Ringer's acetate solution or 100 ml of 20% albumin during the induction of anaesthesia. Blood and urine sampling is performed on three occasions on the day of surgery.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Changes in urine markers of kidney injury (NGAL, microglobulin, albumin, creatinine and erythrocytes). Urine sampled at baseline and 4 hours after surgery has ended

Secondary outcome measures

- 1. The effect of albumin and crystalloid fluid on the colloid osmotic pressure, measured at baseline, the beginning of the surgery, and 4 hours after the surgery
- 2. Surgical complications, measured when the patient leaves the hospital

Overall study start date

01/09/2014

Completion date

30/09/2015

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria

- 1. Males and females with hip fracture who are planned for acute surgery
- 2. Age range 70-90 years

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

40 patients, based on that some increase in kidney injury markers occur in half of our patients (pilot study)

Key exclusion criteria

- 1. Kidney disease
- 2. Serious heart failure (NYHA class III)
- 3. Those undergoing surgery under general anaesthesia
- 4. Poor understanding of the Swedish language

Date of first enrolment

01/09/2014

Date of final enrolment

30/09/2015

Locations

Countries of recruitment

Sweden

Study participating centre Research Unit, House 18

Södertälje Sweden 15286

Sponsor information

Organisation

Stockholm County Council (Sweden)

Sponsor details

Hantverkargatan 45 Box 22550 Stockholm Sweden 10422

Sponsor type

Government

Website

http://www.forskningsstod.sll.se/Ansokan/start.asp

ROR

https://ror.org/02zrae794

Funder(s)

Funder type

Government

Funder Name

Stockholm County Council (Sweden), grant 20130297

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | | Date added | Peer reviewed? | Patient- facing? |
|-------------------|-------------------------------------------------------------------------------------------------|----------------|----------------|----------------|---------------------|
| | observational substudy data examining relationships between potential | | | | |
| Other publication | markers of poor outcome, such as kidney injury and mortality, in hip <u>s</u> fracture patients | 03/06 /2015 | 23/02 /2023 | Yes | No |