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

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
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Contact information

Type(s)
Scientific

Contact name
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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
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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 created	Date added	Peer reviewed?	Patient-facing?
Other publications	observational substudy data examining relationships between potential markers of poor outcome, such as kidney injury and mortality, in hip fracture patients	03/06/2015	23/02/2023	Yes	No