Pilot: Use of Rotem in revisions of hip arthroplasties: Changes in coagulation parameters?

Published: 07-07-2014
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Changes in the Fibtem measurements during the first 24 hours after the start of the operation.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON40640

Source
ToetsingOnline

Brief title
Coagulation in revision surgery

Condition

- Bone and joint therapeutic procedures

Synonym
blood coagulation, fibrinogen

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Innovatiefonds Isala

Intervention

Keyword: coagulation, Hiprevision, Rotem

Outcome measures

Primary outcome

Changes in the Fibtem measurements of the Rotem

Secondary outcome

Changes in the other parameters of the Rotem measurements

Study description

Background summary

Patients who are receiving a total hip replacement will lose a lot of blood in the perioperative period. The bloodloss can exceed the 2 litres. A lot of this patients will receive blood products to compensate the blood loss. A result of this can be postoperative woundinfection. By investigation the coagulation cascade at total hip revisions it maybe possible to decraese the amount of blood products that has to be given. As a result a decrease in wound infection can be seen.

Study objective

Changes in the Fibtem measurements during the first 24 hours after the start of the operation.

Study design

Single centre prospective observational study design

Study burden and risks

No risk for the patient
Besides the routine blood measurements two vena punctions will be done. These blood samples will be taken at the start of the operation and after one hour.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

all patients, older than 18 years, who will receive a total hip revision operation

Exclusion criteria

patient refusal

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-02-2014
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-07-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL47584.075.14