

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

Published: 07-07-2014

Last updated: 20-04-2024

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Bone and joint therapeutic procedures
<b>Study type</b>	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

### Public

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NL

### Scientific

Isala Klinieken

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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**

CCMO

**ID**

NL47584.075.14