Evaluating the role of WBC scintigraphy in monitoring response on infection treatment of prosthetic joint infection

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To evaluate the role of white blood cell (WBC) scintigraphy in monitoring the response of infection treatment of a prosthetic joint infection.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Ancillary infectious topics
Study type	Observational non invasive

Summary

ID

NL-OMON43167

Source
ToetsingOnline

Brief title
WBC scan in infected prosthetic joints

Condition

- Ancillary infectious topics
- Joint disorders

Synonym
prosthetic joint infection; infected hip or knee prosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: GE Healthcare

Intervention

Keyword: prosthetic joint infectioin, treatment response, WBC scintigraphy

Outcome measures

Primary outcome

The number of re-infections of a prosthetic joint one year after reimplantation. In the cases with a relapse of infection (caused by the same micro-organism(s)), the diagnostic value of the WBC scintigraphy in monitoring the response of infection treatment will be evaluated to define if WBC scintigraphy can help in deciding when to perform the reimplantation.

Secondary outcome

Not applicable

Study description

Background summary

The incidence of a prosthetic joint infection after revision surgery is approximately 30%. There is no consensus about the timing of reimplantation of a new prosthetic joint after removal of an infected prosthesis. To verify the absence of residual infection before re-implanting a new prosthesis is important in order to prevent a re-infection of the new prosthesis.

Study objective

To evaluate the role of white blood cell (WBC) scintigraphy in monitoring the response of infection treatment of a prosthetic joint infection.

Study design

In all patients, a WBC scintigraphy will be performed in the 3rd week after removal of the prosthesis. Additionally, in patients who follow a long interval before reimplantation a 2nd WBC scintigraphy is repeated 1 week before the surgery. At the same day of the scintigraphy, inflammatory parameters (c-reactive protein (CRP) will be measured and clinical parameters will be

recorded.

Study burden and risks

The extent of burden and risks for patients participating in the study is considered low. If the WBC scintigraphy turns out to be of value in the monitoring of treatment response during an infection, the WBC scintigraphy will be implemented in a flowchart of standard care, in order to safely reimplant a new prosthesis.

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

Patients >= 18 years, who undergo a 2-stage revision surgery (with a short or long-interval) because of an infected prosthesis of the knee or hip. The indication for a 2-stage revision surgery, as well as the decision for a short or long interval, depend on several (clinical) parameters and is made by a multidisciplinary expert team.

Exclusion criteria

Patients < 18 years, and pregnant or lactating women will be excluded from this study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-10-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL57331.042.16