

MORE DATa study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24413

Source

NTR

Brief title

MORE DATa

Health condition

total hip arthroplasty, knee arthroscopy, immune response, monocyte populations

Sponsors and support

Primary sponsor: Martini Hospital Groningen

Intervention

Outcome measures

Primary outcome

Expression of early and late markers that identify the maturation stage of monocyte subpopulations.

Secondary outcome

- Absolute numbers of monocyte subpopulations and lymphocyte populations.

- Serum interleukines and classical tissue damage marker (CRP and CK) levels.

Study description

Background summary

Information on the extent of tissue damage after trauma, surgery, disease or therapy is an important parameter in the clinical evaluation of patients and can prevent complications. Unfortunately currently no reliable minimal invasive methods exist to examine such tissue damage. New insights in the kinetics of blood leukocytes after surgical procedures have shown that monitoring of tissue damage can be performed via small amounts of peripheral blood – the monocyte subpopulations change remarkably in the early phase after surgery. Patients after total hip replacement demonstrated a massive increase of classical monocytes after a notable decrease, 24 hours after surgery. A possible explanation for this phenomenon could be massive recruitment from the bone marrow after large numbers of blood monocytes have migrated into the tissue. This bone marrow recruitment would then resemble the granulocytic left-shift that can be found during or after acute infections. If this hypothesis is correct, a large proportion of the classical monocytes should have a more ‘immature’ phenotype.

This study will evaluate the monocyte phenotype at several time points after a total hip replacement surgery (severe tissue damage) and a knee arthroscopy (minimal tissue damage).

Study objective

The existence of a “monocyte left-shift” after (severe) tissue damage.

Study design

5mL of peripheral blood will be drawn preoperatively and postoperatively, with a small margin, at 2 hr, 6 hr, 24 hr, 36 hr, 48 hr and 1 week.

Intervention

5mL of peripheral blood will be drawn preoperatively and postoperatively, with a small margin, at 2 hr, 6 hr, 24 hr, 36 hr, 48 hr and 1 week. After blood samples have been obtained from the patients, the material will be transported at 4°C to the LUMC laboratory site for analysis.

Contacts

Public

University Medical Center Groningen (UMCG), Department of Anesthesiology,
P.O. Box 30001
A.J. Vries, de
Hanzeplein 1
Groningen 9700 RB
The Netherlands
+31 (0)50 3616161

Scientific

University Medical Center Groningen (UMCG), Department of Anesthesiology,
P.O. Box 30001
A.J. Vries, de
Hanzeplein 1
Groningen 9700 RB
The Netherlands
+31 (0)50 3616161

Eligibility criteria

Inclusion criteria

- elective knee arthroscopy or an elective total hip arthroplasty (posterolateral approach) for primary osteoarthritis
- between 18 and 70 years of age
- signed informed consent

Exclusion criteria

- pre-existing immune deficiency
- use of immunosuppressant drugs
- orthopaedic surgery in the last two years
- cognitive impairments
- Evident infectious complications such as pneumonia, surgical site infection (SSI) and/or urinary tract infection (UTI), during postoperative course

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2018
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion	
Date:	18-07-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47488
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7207
NTR-old	NTR7406
CCMO	NL60718.099.18
OMON	NL-OMON47488

Study results