Synovial immune alterations and biomarkers of arthritis

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- to investigate different cellular, molecular, genetic and epigenetic pathogenic mechanisms in synovial tissue leading to the various inflammatory joint diseases- to investigate these changes in the synovial tissue in relationship to the duration...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON55559

Source ToetsingOnline

Brief title Synovial immune alterations and biomarkers of arthritis

Condition

- Autoimmune disorders
- Joint disorders

Synonym arthritis, rheumatoid arthritis

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: collectebusfondsen

Intervention

Keyword: arthritis, biomarkers, mini-arthroscopy, synovium

Outcome measures

Primary outcome

- to investigate pathogenic mechanisms in synovial tissue
- to investigate these changes in the synovial tissue in relationship to the

duration and different stages of inflammatory joint diseases

- to investigate the relationship between these changes in the synovial tissue

with changes in systemic immunity in different stages and forms of inflammatory

joint diseases

- to identify new therapeutic targets in the synovial tissue
- to identify new diagnostic and prognostic markers in synovial tissue.

Secondary outcome

N.A.

Study description

Background summary

In different types of inflammatory arthritis including rheumatoid arthritis (RA), spondyloarthritis, crystal-induced arthritis and some forms of osteoarthritis, for example, the synovium is hypertrophic and edematous. Since RA and other arthritides primarily involve the synovium, synovial tissue analysis provides insight into the pathogenesis of the disease process. Descriptive studies of the inflamed synovium as well as in vitro functional analyses of cells obtained from inflamed synovium contribute to an understanding of the unique events that take place in vivo and complement experimental animal studies and fundamental studies. Moreover, such studies allow to identify immune and stromal alterations that are unique to the joint and can not been found in more accessible tissue compartments such as the peripheral blood.

Study objective

- to investigate different cellular, molecular, genetic and epigenetic pathogenic mechanisms in synovial tissue leading to the various inflammatory joint diseases

- to investigate these changes in the synovial tissue in relationship to the duration and different stages of inflammatory joint diseases

- to investigate the relationship between these changes in the synovial tissue with changes in systemic immunity (ie., blood and SF) in different stages and forms of inflammatory joint diseases

- to use this knowledge to identify new therapeutic targets in the synovial tissue in different stages and forms of disease

- to use this knowledge to identify new diagnostic and prognostic markers in synovial tissue in inflammatory joint diseases.

Study design

One center study with the aim to include 300 patients.

single visit study: medical history and medication use en a questionnaire about disease activity, physical examination, blood drawing, mini-arthroscopy, and if available, also synovial fluid will be drawn during mini-arthroscopy.

Study burden and risks

Blood drawing and synovial fluid aspiration has no extra risks since these are standard care procedures if a patient has an arhtriits. Only extra blood will be drawn and synovial fluid is not thrown away in this study. Furthermore a mini-arthroscopy will be done to perform a therapeutic lavage in a partical inflammatory joint, which is very helpfull for the patient. The extra thing done for this study is obtaining small biopsies which the patient will not feel.

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

- 18 years or older

- diagnosis of peripheral arthritis

- active (drug resistant) inflammation of at least a (therapy resistant) knee or ankle joint.

Exclusion criteria

patients unable to give informed consent

Study design

Design

Study type: Observational invasiveMasking:Open (masking not used)Control:UncontrolledPrimary purpose:Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	09-09-2013
Enrollment:	300
Туре:	Actual

Ethics review

Approved WMO	
Date:	23-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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** NL44195.018.13