Feasibility of aspiration of Ultrasound guided Synovial fluid from Inflamed Small hand joints.

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To investigate the feasibility of aspirating synovial fluid from small hand joints, such as interphalangeal and MCP joints of patients with hand OA and inflammatory diseases who are referred for an intra-articular injection of an inflamed joint.

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

Summary

ID

NL-OMON53105

Source
ToetsingOnline

Brief title
Feasibility of US guided aspiration from inflamed small hand joints/ FUSIS

Condition

- Joint disorders

Synonym
osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aspiration, Hand joints, Synovitis, Ultrasound

Outcome measures

Primary outcome

• The percentage of study joints in which a successful aspiration is performed.

Secondary outcome

• The volume of the obtained synovial fluid collections (µl).

• To analyse the presence of cytokines (such as IL-1, IL-6, IL-8, TNF-α), of immune cells (neutrophils, macrophages, lymphocytes) and adipokines and lipid mediators in the synovial fluid.

• The relation between the US effusion score and volume of synovial fluid that is aspirated from the study joint.

Other study parameters

• Association of physical and ultrasound inflammatory/structural features and the ability to obtain synovial fluid (i.e. obesity, big structural abnormalities, such as osteophytes or joint space narrowing)

• To investigate whether there is a difference in feasibility, amount of synovial fluid and analyses between hand OA and inflammatory arthritis (rheumatoid arthritis and psoriatic arthritis)

Study description

Background summary

Hand osteoarthritis (OA) is a prevalent disease of which the aetiology is largely unknown. Synovitis can frequently be found in hand joints of OA patients with the use of imaging modalities such as ultrasonography (US). Although synovitis is thought to be involved in clinical features and development of structural damage, its exact role is currently not elucidated. Therefore, the investigation of synovial tissue would be of great interest. However, synovial tissue can only be obtained via an invasive procedure, which is not easy in small hand joints. Alternatively, it might be possible to obtain synovial fluid, which is a reflection of the processes going on in the synovial tissue, and is therefore also of interest to study.

Study objective

To investigate the feasibility of aspirating synovial fluid from small hand joints, such as interphalangeal and MCP joints of patients with hand OA and inflammatory diseases who are referred for an intra-articular injection of an inflamed joint.

Study design

The study is set up as a pilot study, to investigate the feasibility of aspirating synovial fluid from inflamed small hand joints of patients with OA, rheumatoid arthritis and psoriatic arthritis. It is a single centre study and patients will be recruited consecutively from the outpatient clinic of the department of Rheumatology, Leiden University Medical Centre.
Patients suffering from OA, rheumatoid arthritis or psoriatic arthritis, that are planned to have an intra-articular injection in usual care of one of the small hand joints (interphalangeal joints or MCP joints), the study joint by their treating doctor, will be asked to participate. If the patient is willing to participate, an US examination will be performed of the study joint and inflammatory features (effusion, synovial thickening and Doppler signal) will be scored semi-quantitatively. A puncture will be performed of the study joint and aspiration of synovial fluid will be tried. If synovial fluid is aspirated, it will be collected and transferred to a glass vial.. Subsequently, a corticosteroid injection will be given into the study joint.

Study burden and risks

Only patients that are already planned to have an injection in an inflamed MCP or interphalangeal joint will be included. The puncture to obtain synovial fluid will be performed before the injection with corticosteroids takes place, and whenever possible the syringe will be changed so that the patient will be only punctured once, instead of performing another puncture.
Benefits for the patients will be the fact that using US, the needle can be placed under vision exactly within the inflamed joint allowing the medication to be placed exactly where it is intended to be, while the chance of having a

complication is diminished (for instance due to the visualisation under US guidance of the bone or blood vessels, the chance of damaging these tissues is diminished.) It is thought that the US guided procedure is therefore less painful and more effective.

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

1. Diagnoses of hand OA, rheumatoid arthritis, or psoriatic arthritis according to recognised classification criteria sets
2. Presence of an inflamed interphalangeal or MCP joint for which the treating rheumatologist has proposed treatment with an intra-articular injection with corticosteroids.

3. Patients should be 40 years of age or older.

Exclusion criteria

1. Patients that had an intra-articular injection with corticosteroids, an operation or an important trauma in the same joint less than 12 weeks before the intended injection
2. The presence of a chronic inflammatory disease (other than OA, rheumatoid arthritis or psoriatic arthritis), such as poly-articular gout
3. Contra-indication for an intra-articular injection such as anti-coagulant (vitamin K antagonist) use that can*t be discontinued.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-05-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	18-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26127
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61359.058.17
OMON	NL-OMON26127