

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

No registrations found.

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

Summary

ID

NL-OMON26127

Source

Nationaal Trial Register

Brief title

FUSIS

Health condition

Hand osteoarthritis (OA), rheumatoid arthritis (RA) and psoriatic arthritis (PsA) patients.

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The volume of the obtained synovia) fluid collections (~l);

- To analyse the presence of cytokines (such as IL-1, IL-6, IL-8, TNF-a), of immune cells (neutrophils, macrophages, lymphocytes) and adipokines and lipid mediators in the synovia) fluid;
- The relation between the US effusion score and volume of synovia) fluid that is aspirated from the study joint.

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 synovia/ tissue would be of great interest.

However, synovia/ tissue can only be obtained via an invasive procedure, which is not easy in small hand joints. Alternatively, it might be possible to obtain synovia/ fluid, which is a reflection of the processes going on in the synovia/ tissue, and is therefore also of interest to study.

Study objective

To investigate the feasibility of aspiration of synovia/ fluid from inflamed small OA hand joints and in case synovia/ fluid can be obtained, to investigate which analyses can be performed on the amount of fluid obtained.

Study design

single study visit

Intervention

not applicable

Contacts

Public

Scientific

Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2018
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion	
Date:	01-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53105
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7283
NTR-old	NTR7517
CCMO	NL61359.058.17
OMON	NL-OMON53105

Study results

Summary results

not yet applicable