# Ultrasound-guided biopsy from hand joints in arthralgia or arthritis patients: a feasibility study

Published: 13-01-2021
Last updated: 21-12-2024

To determine the feasibility of performing US-guided synovitis and tenosynovitis in wrist and MCP-joints, and investigate the quality and quantity of the obtained tissues.

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

## Summary

### ID

NL-OMON51914

**Source**
ToetsingOnline

**Brief title**
Biopsy from hand joints

### Condition

- Autoimmune disorders

**Synonym**
arthralgia, arthritis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** derde of vierde geldstroom

## Intervention

**Keyword:** Arthralgia, Arthritis, Hand joint inflammation, Ultrasound-guided biopsy

## Outcome measures

### Primary outcome

Success rate of US-guided synovitis and tenosynovitis biopsy, which is based on

the quality and quantity of the obtained tissues.

### Secondary outcome

NA

# Study description

### Background summary

The mechanisms underlying arthritis becoming chronic are poorly understood. The development of rheumatoid arthritis (RA) is considered to be a multiple-hit process that is largely taking place before the disease presents with clinically swollen joints. The disease is characterised by inflammation of synovium, preferentially the joints of the hands. Research, from our own department using MRI, showed that RA is also characterized by inflammation of the tenosynovium, as tenosynovitis is present in >85% of RA-patients at the time of diagnosis. Furthermore tenosynovitis is one of the first features of developing RA. Tissue research has so far focussed on synovitis, using established molecular techniques on biopsies from patients with established disease. Ultrasound (US)-guided synovial biopsy techniques have been developed, also for hand joints, and proved reliable, minimally invasive, well-tolerated and safe when grade 2 inflammation is present. Whilst established molecular techniques require relatively large tissue samples, novel techniques have developed, such a single cell sequencing and imaging mass cytometry, which provide unprecedented possibilities to discover (novel) cells characterizing disease and require only small tissue fragments. This would allow to perform molecular studies of synovitis and tenosynovitis from hand joints in patients in early phases of RA. Other European groups performing US-guided biopsies, showed that sufficient material for analyses could be obtained in ~60-90% of patients biopsied, and that this material was representative of the joint status in small joints of RA-patients. We aim to determine if it is feasible in our center to perform US-guided synovitis and tenosynovitis biopsies in the metacarpophalangeal (MCP)- or wrist joints with grade 2 inflammation and

analysis the obtained tissues. If successful we aim to expand the study in patients with early stages of RA to enhance our understanding of RA-pathogenesis and promote subsequent development of targeted therapies

**Study objective**

To determine the feasibility of performing US-guided synovitis and tenosynovitis in wrist and MCP-joints, and investigate the quality and quantity of the obtained tissues.

**Study design**

This is a cross-sectional observational study.

**Study burden and risks**

Patients will have US-guided biopsy. Patients will have no benefits when participating in this study. Results, which are molecular analyses of (teno)synovium tissue, will not be communicated to rheumatologists or patients.

# Contacts

**Public**
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
**Scientific**
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Patients referred to rheumatology outpatient clinic (LUMC).
- Age >=18 years.
- Grade >=2 synovitis or tenosynovitis.
- Consent to comply with the requirements of the study protocol.

## Exclusion criteria

- Contraindications to ultrasound-guided biopsy, such as active skin infection and anticoagulant/antiplatelet treatment.
- Known for lidocaine-allergy

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 13-04-2021 |
| Enrollment: | 30 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 13-01-2021 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 27-10-2022 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL75734.058.20 |