Arthroscopic Synovectomy versus Intra-articular Injection of Corticosteroids for the Management of Therapy Refractory Psoriatic or Rheumatoid Arthritis of the Wrist: a Randomized Controlled Trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON56165

Source
ToetsingOnline

Brief title
ARCTIC

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
rheumatiod and psoriatic arthritis of the wirst, wrist arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Er lopen beursaanvragen bij reumatologie fondsen

Intervention

Keyword: Psoriatic arthritis, Rheumatoid arthritis, Synovectomy, Wrist arthroscopy

Outcome measures

Primary outcome

Patient-Rated Wrist Evaluation (PRWE), 3 months after intervention

Secondary outcome

- DAS28 score

- Resolution of synovitis measured with ultrasound (using the EULAR-OMERACT

combined scoring system)

- Wrist damage measured with plain wrist radiographs

- Range of motion (ROM) and grip strength of the wrist

- Quality of life measured with the EQ-5D

- Cost-effectiveness analysis calculated with the EQ-5D, iMCQ and iPCQ

Study description

Background summary

Psoriatic (PsA) and rheumatoid arthritis (RA) are inflammatory joint diseases that often involve the wrist and may result in progressive joint destruction followed by impaired wrist function and reduced quality of life. The first line treatment consists of conventional Disease-Modifying Anti-Rheumatic Drugs (cDMARDs) along with bridging therapy using systemic corticosteroids or intra-articular corticosteroids. After initiation of therapy, intra-articular corticosteroid injections are often utilized as they provide rapid dampening of joint inflammation in case of a localized flare of disease activity (mono- or

oligoarthritis). However a substantial part of these patients clinically respond poorly or not at all. Alternatively, arthroscopic synovectomy is a low risk intervention that may provide substantial relieve of symptoms, improve functionality, slow down disease progression and prevent joint destruction, as earlier studies have suggested. Prospective randomized studies are needed to confirm these findings. Moreover, arthroscopic synovectomy may prevent the need for expensive biological (b)DMARDs and assist in guiding therapeutic strategies in the long run, through collecting and analyzing valuable synovial biopsies.

Study objective

The objective of this study is to demonstrate that arthroscopic synovectomy of the wrist comined with deposition of intra-articular corticosteroids (DIACS) will lead to better functional outcomes compared to intra-articular corticosteroid injection (IACSI) in cDMARD resistant RA and PsA patients.

Study design

The ARCTIC-trial is a multicenter randomized controlled trial in the Maastad hospital in Rotterdam, Spijkenisse Medisch Centrum (SMC) in Spijkenisse, Erasmus Medical Center (EMC) in Rotterdam, Franciscus Gasthuis & Vlietland (FGV) in Rotterdam, Leiden University Medical Center (LUMC) in Leiden, Albert Schweitzer hospital in Dordrecht (ASZ), Amphia hospital in Breda (AZ), van Weel Bethesda Hospital (vWB) in Dirksland, IJsselland Hospital (YSZ) in Rotterdam and Haaglanden Medical Center (HMC) in Den Haag. Study inclusion and follow-up will take place in the Maasstad hospital. The EMC, FGV, LUMC, ASZ, AZ, vWB, YSZ and HMC will only prescreen patients and not perform any study procedures. Wrist arthroscopies will be performed in the Maasstad hospital and in the SMC. Because the intervention involves surgery, the study will not be blinded.

Intervention

This study will randomize between arthroscopic synovectomy of the wrist combined with deposition of intra-articular corticosteroids (DIACS) and intra-articular corticosteroid injection (IACSI) of the wrist.

Study burden and risks

Risks:
The intervention group will receive wrist arthroscopy, which is often implemented for intra-articular wrist pathology. The risks include those related to anaesthesia, infection, neurovascular damage and articular surface damage. Nevertheless, wrist arthroscopy is a well-established and safe technique. Close follow up and a protocol of treatment, identical to the standard one, will be applied in every subject. Reduction of risks will be done according to inclusion and exclusion criteria. If complications arise, the

treating physician will proportionate the adequate treatment according to the current protocols of treatment based on the published literature.
IACSI is standard treatment of care. Risks are very low and include hemorrhage, infection and pain at the injection site.

Burden:
Patients will be asked to return at 3, 6 and 12 months. These visits are standard of care following the rheumatic arthritis protocol. During these visits, patients will be asked to complete 3 questionnaires. This will take 40 minutes for each visit (including baseline measurements, this will be 160 minutes in total). The arthroscopy group will return between 10-14 days for wound inspection, which is standard. All patient will be contacted by telephone at 2, 4 and 6 weeks for VAS pain scores, which will take no longer than 5 minutes.
Anti-rheumatic therapy will be temporarily stoppen before intervention and cannot be changed in the first three months after intervention.

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

Inclusion criteria:
- Male and female patients that are 18 years or older
- Patients are diagnosed with rheumatoid arthritis according to the revised 2010 ACR/EULAR Rheumatoid Arthritis Classification Criteria or with psoriatic arthritis according to the CASPAR criteria
- Patients are experiencing an exacerbation defined as an increase in DAS28 > 1.2 or > 0.6 if DAS28 >= 3.2 compared to last DAS28 measurement (maximum 6 months before), or an exacerbation clinically diagnosed by a rheumatologist.
- Wrist arthritis, that is clinically diagnosed, is the predominant symptom
- Patients with an exacerbation, either under cDMARD treatment or no treatment specified as:
• Patients with an exacerbation and are stopped with cDMARD treatment in the past due to side-effects or no effect from cDMARD treatment.
• Patients with an exacerbation and can*t start cDMARD treatment due to contra-indications for cDMARD treatment.
• Patients with a mono- or oligoarthritis as an exacerbation and have stopped cDMARD treatment in the past due to disease in remission. First choice of treatment in case of mono- or oligoarthritis can be local treatment before restart systemic cDMARD treatment.

Exclusion criteria

- Current treatment or treatment within the last 12 months with biological (b)DMARDs
- Current inflammatory joint disease other than RA or PsA (e.g., gout, reactive arthritis, Lyme disease)
- Subjects who are pregnant or intend to become pregnant during the study
- Intra-articular corticosteroids injection in the wrist in the last 3 months.
- Previous wrist surgery
- Severe osteoarthritis with malformations of the wrist
- Congenital abnormalities of wrist function or motion
- Patients with arthritis in both wrists can only participate in the study with one wrist

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-02-2021
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-01-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-06-2021
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-09-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-07-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-08-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-08-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL74744.100.20