Platelet Rich plasma Injection Management for Ankle osteoarthritis study (PRIMA): A multi-center, stratified, block-randomized, double-blind, placebo-controlled trial

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The goal of this study is to determine the efficacy of PRP injections in the management of ankle osteoarthritis by comparing 2 groups: One receiving a PRP injection and the other a saline solution.

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

Summary

ID

NL-OMON50206

Source
ToetsingOnline

Brief title
PRIMA

Condition

- Joint disorders

Synonym
osteoarthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ankle, injection, osteoarthritis, PRP

Outcome measures

Primary outcome

American Orthopaedic Foot and Ankle Society (AOFAS) score at 26 weeks

follow-up, validated scale for ankle OA (0-100) measuring three subdomains

(pain, function and alignment).

Secondary outcome

1. Pain scores: (VAS 0-100) during activities of daily living and the pain

sub-scale of AOFAS (0-40)

2. Ankle activity score (0-10)

3. Subjective patient satisfaction (4 categories)

4. Health related quality of life (SF-36 scale)

5. The Global Attainment Scaling (GAS)

6. EQ-5D-3L utility score

7. Ankle Osteoarthritis Score (AOS)

8. Foot and Ankle Outcome Score (FAOS)

Study description

Background summary

Pain is the cardinal symptom of ankle osteoarthritis (OA) and is a complex

phenomenon with limited understanding of its pathomechanisms. The main objectives in the clinical management of OA are to reduce inflammation and cartilage degeneration processes and relieve pain.
A recent review concluded that in animal models platelet rich plasma (PRP) can diminish multiple inflammatory IL-1 mediated effects, and can also positively influence the collagen network of the cartilage and subsequently reduce pain and improve function.
Our recent and other systematic reviews showed that compared to placebo injections, hyaluronic acid or corticosteroid injections, PRP injections significantly decrease pain and improve function in knee OA. Given the clinical effect on pain reduction in OA and safety, PRP might serve as a promising non-surgical therapy and might potentially delay the irreversible surgical option of arthrodesis.

Study objective

The goal of this study is to determine the efficacy of PRP injections in the management of ankle osteoarthritis by comparing 2 groups: One receiving a PRP injection and the other a saline solution.

Study design

A multi*center, stratified, block*randomized, double*blind, placebo*controlled trial comparing two treatment groups.

Intervention

In this study, patients will be randomised into two treatment groups: PRP injection or placebo injection. Treatment allocation will be concealed. Two double syringes of autologous blood will be collected twice with from the cubital vein: at inclusion and at a time interval of 6 weeks. This blood will be prepared according to the instructions of the manufacturer (see below PRP preparation), and the injection will be given within 30 minutes after preparation. For each injection 2 ml will be injected into the affected ankle joint under ultrasonographic guidance. The control group will follow exactly the same protocol of vena puncture and preparation of the PRP, but instead of PRP, 2ml physiological saline will be injected on each occasion. To guarantee blinding for the allocated treatment of the patient, treatment assessor and treating physician, blood will be drawn and PRP will be prepared for each patient during both injections (at inclusion and at a time interval of 6 weeks after the first injection). A research assistant will select one of the two syringes based on the allocated intervention and blinds the syringe with a covering sheath.

Study burden and risks

Complications have not been observed in previous studies with the same intervention performed on different locations. The PRP injection may be painful but similar to other inta-articular injections. Although no adverse effects have been previously reported, no guarantee can be given for intra-articular ankle injections. On inclusion, participants will undergo ankle x-rays. The expected radiation and risks to the participant as a result are negligible.

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

- Severity of Ankle OA pain on a visual analogue scale (VAS) (0-100 mm) >= 40 during daily activities
- X-rays (AP and lateral view) indicating >= grade 2 on the Van Dijk classification

- Age >= 18 years

Exclusion criteria

- Patient has received injection therapy for ankle OA in the previous 6 months
- Patient does not want to receive one of the two therapies
- Patient has clinical signs of concomitant OA of one or more other major joints of the lower extremities that negatively affects their daily activity level
- Previous ankle surgery for OA or Osteochondral defects (OCD) < 1 year (not including surgery for an ankle fracture in the past)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-08-2018
Enrollment:	112
Type:	Actual

Medical products/devices used

Generic name:	Plasma-rich platelet injection (PRP injection)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2020
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	ID
ClinicalTrials.gov	NCT01812564
CCMO	NL64160.018.18