Patients with knee pain caused by osteoarthritis: Comparison of conservative Medical Management with RadioFrequency ablation or chemical neurolysis of the genicular nerves with Phenol.

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Primary Objective: • To compare the efficacy of chemical ablation with phenol and RFA of the genicular nerves with conservative treatment in patients with chronic knee pain caused by OA, on the Oxford Knee Score (OKS) at six months follow…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53980

Source
ToetsingOnline

Brief title
RADIOPHENOL

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
chronic knee pain, Osteoarthritis

Health condition

zenuwblokkade voor behandeling chronische knie pijn

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Dijklander hospital;department of Anesthesiology

Intervention

Keyword: Chemical neurolysis, Genicular nerves, Knee pain, Radiofrequency Ablation

Outcome measures

Primary outcome

The primary study parameter, the OKS (Oxford Knee Score) will be collected at baseline, and at 6 weeks, 3 months, 6 months and 12 months after the intervention.

The OKS is scored in different ways. We will use the 0 to 48 system which is considered the best. In this system each question is scored between 0 and 4, with 4 being the best outcome. This produces overall scores from 0 to 48, with 48 being the best outcome and a lower score indicates more functional limitations and pain.

Secondary outcome

1. The WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) will be collected just before the genicular nerve ablation, and at 6 weeks, 3 months, 6 months and 12 months follow up.

2. Pain in rest and during the performance based tests will be measured with the NRS.

3. Three Performance based tests

• 30 second chair stand test (30-s CST):

• 40 meters (4x10m) fast-paced walk test (40-m FPWT):

• 9-steps stair-climb test (9-step SCT):

4. The EQ-5D-5L questionnaire.

5. Anxiety and depression measured by the Hospital Anxiety and Depression Scale (HADS)

6. Catastrophizing measured by the Pain Catastrophizing Scale (PCS)

7. The cut-off value for the diagnostic block

8. The patient satisfaction with the result of treatment will be measured with a 5-point Likert scale (1-5). T

9. The Patient Global Impression of Change (PGIC) in pain and function will be measured with a 5-point Likert scale (1-5).

10. MCID: We will use distribution and anchor based methods to determine the MCID on the patient reported outcomes OKS and performance based tests. For the EQ-5D-5L we will use an instrument defined method.

11.Adverse events: The reported treatment related or probably treatment related adverse events will be listed as numbers with frequencies per treatment.

12. Medication: The patients will be asked to report changes in the use of NSAIDs and opioids during the follow-up visits. The results will be summarised as increased use, no change, decrease in use and use of opioids will be reported as MME (Morphine Milligram Equivalents).

13. The number of TKAs (total knee arthroplasties) during the study follow-up will be documented including the point in time since the intervention. If applicable, we will use the Kaplan-Meier estimator to estimate the survival function.

14. The total procedure time of chemical ablation and RFA will be measured in minutes. The measurement starts as soon as the treating physician puts on his sterile gloves and will end when the sterile draping is taken off.

15 Other study parameters patient characteristics: Height, weight, Age at procedure, Alcohol and tobacco use, Sex.

16 Discomfort score: At the end of the intervention (T=0) the patient will be asked to rate the discomfort during procedure on a 5-point Likert scale.

Study description

Background summary

In guidelines for knee osteoarthritis (OA), conservative treatments are physical therapy, analgesics and intra-articular injections with corticosteroids. In severe OA and persisting symptomatic cases the golden standard is joint replacing surgery. A less invasive technique is ablation of the sensory (genicular) nerves of the knee. This technique is beneficial for younger patients as a bridge to surgery or patients that cannot undergo knee arthroplasty due to comorbid health conditions. Nerve ablation can either be done with chemical agents or thermal energy.

Although there are numerous studies on genicular nerve block for chronic knee pain caused by OA, there are just a few small studies that compare genicular nerve block with conservative treatment.

To be able to determine if genicular nerve ablation is efficacious to serve the gap between conservative treatment and TKA, this randomised controlled trial (RCT) compares two forms of genicular nerve ablation (radiofrequency and phenolisation; intervention) with conservative treatment (control) up to 6

months after treatment.

Study objective

Primary Objective:
• To compare the efficacy of chemical ablation with phenol and RFA of the genicular nerves with conservative treatment in patients with chronic knee pain caused by OA, on the Oxford Knee Score (OKS) at six months follow up

Secondary Objective(s)

1. To evaluate the effects of chemical ablation of the genicular nerves with phenol, RFA of the genicular nerves and conservative treatment in patients with chronic knee pain caused by OA over time on:
a. Knee function measured by the OKS
b. Evaluation of OA measured by the Western Ontario and McMaster Universities Arthritis Index (WOMAC)
c. Pain measured by a numeric rating scale (NRS) in rest and during activity (performance based tests)
d. Performance as measured by three performance based tests
1. 30 seconds chair-stand test (30-s CST)
2. 40 meters fast-paced walk test and (40-m FPWT)
3. the 9-steps stair-climb test (9-step SCT)
e. Health related quality of life measured by the Euroqol 5 dimensions 5-level (EQ-5D-5L) questionnaire.
f. Anxiety and depression measured by the Hospital Anxiety and Depression Scale (HADS)
g. Catastrophizing measured by the Pain Catastrophizing Scale (PCS)
2. To determine the most appropriate cut-off value of the result of the diagnostic block to predict a positive response to ablation
3. To evaluate patient satisfaction with the treatment and with the outcome
4. To evaluate patient global impression of change (PGIC)
5. To evaluate the minimum clinically important difference (MCID) for the OKS, the WOMAC, the performance based tests and the EQ-5D-5L in our population
6. To evaluate possible adverse events
7. To evaluate changes in the use of non-steroidal anti-inflammatory drugs (NSAIDs) and opioids (in morphine milligram equivalents (MME))
8. To determine the total number and time-point of TKA procedures during study follow up.
9. To compare the total procedure time of chemical ablation and RFA

Study design

This study is set-up as a multicenter randomised controlled trial with three parallel arms. Patients will be randomly assigned (1:1:1) to radiofrequency ablation (group A), chemical ablation with phenol (group B) or conservative

treatment (group C). All treatments will be performed by experienced pain physicians. Total follow up time after the intervention will be one year for the intervention arms and 6 months for the conservative treatment arm. Data will be collected at various time points.

Intervention

All patients in group A and B wil receive a diagnostic nerve block and will be randomised to either RFA or phenol ablation of genicular nerves.

- Diagnostic blocks will be performed by injection of 1,5ml of Lidocaine 2% at the 3 target site.

- Interventional treatments:

o Treatment group A: Radiofrequency ablation (RFA) is performed by creating two RFA lesions at the 3 treatment sites (6 lesions in total) after local anesthesia with 1.5ml lidocaine 2%. The lesions are made by heating the 5mm active tip of the needle to 80°C for 90 seconds.

o Treatment group B: Chemical ablation with phenol is done by injection of 1,5ml of phenol 6 % at the 3 target sites after infiltration with contrast dye to rule out intravascular injection. Because infiltration with phenol is painless, prior infiltration of the target site with al local anaesthetic is not necessary.

Study burden and risks

Patients undergo 8 centre visits in total, of which 4 visits are additional to standard care. Additional centre visits for study purposes are the informed consent visit (T=-2) and the extended follow up at T2, T3 and T4. The follow up visits consist of functional testing and filling in questionnaires and NRS (30 min per visit). The total follow-up will be 1 year for group A and B and 6 months for group C. Total time burden for patients is estimated to be between 4 and 6 hours in total for group A and B and between 2 and 3 hours for group C.

The study compares three standard care therapies. Based on the AMC-CRU Risicoclassificatie-instrument there is a negligible risk. All treatments are covered by the health care insurance.

Patients in group A and B can benefit from the intervention as it may reduce pain, the use of pain medication and may increase functional parameters as described in the OKS. Patients in group C will have no interventional treatment. They have to wait 6 months before they are allowed to receive an interventional treatment and they might not have benefits from participation in the study.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1100DD
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1100DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Adult patients of both sexes, older then 35 years who are not a candidate for TKA (total knee arthroplasty) due to young age, old age, comorbidity or technical reasons.
2.OKS under 30 on a scale from 0 (severe function) to 48 points (satisfactory function).
3. Continued pain in the target knee that is moderate to severe (defined as NRS >= 6 on an 11-point NRS scale) either constantly or with motion despite at least 3 months of conservative treatments. Conservative treatment can include: active physiotherapy, pharmacological treatment of pain (acetaminophen or NSAIDs) and intra-articular corticosteroid infiltration.
4. Radiologic confirmation of arthritis for the target knee. Defined as the

Kellgren Lawrence (KL) score of 2 or more on X-ray or MRI.

Exclusion criteria

1. Patient with prior ablation of the genicular nerves, prior partial, resurfacing, or total knee arthroplasty of the target knee (residual hardware). 2. Patient with a history of neurovascular injury or recent trauma of the lower extremities. 3. Patient with chronic widespread pain. 4. Polyneuropathy and/or radicular pain in the lower extremities. 5. Patient is currently implanted with a neurostimulator. 6. Local or systemic infection (bacteraemia). 7. Uncontrolled immune suppression. 8. Intra-articular injections (steroids, hyaluronic acid, platelet enriched plasma, stem cell, *) in the target knee within 90 days from randomisation. 9. Arthroscopic debridement/lavage into the target knee within 180 days from randomisation. 10. BMI<18,5 kg/m2 and patients with minimal subcutaneous tissue thickness that would not accommodate ablation with phenol or radio frequency (risk of skin burns). 11. Allergies to products used during the procedure (lidocaine, phenol, contrast dye). 12. Patients who have a planned TKA in the near future, defined as patients who already have agreed on a date for the TKA procedure. 13. Patients with psychosocial problems as determined by the investigator. 14. Patients who are not able to perform the performance based tests as determined by the investigator.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2023
Enrollment:	192
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2024
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	NCT06094660
CCMO	NL83410.018.22