Effectiveness of radiotherapy in osteoarthritis of the hand and knee

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21389

Source
Nationaal Trial Register

Brief title
RadiO

Health condition

Osteoarthritis, Degenerative joint disease, Arthritis, Hand, Knee, Knie, Artrose, Gewrichtsslijtage

Sponsors and support

Primary sponsor: Sint Maartenskliniek Nijmegen
Source(s) of monetary or material Support: sponsor

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the percentage of responders according to the 2004 OMERACT-OARSI responder criteria (Pham 2004), 14 weeks after baseline: either improvement in pain or function ≥50% and an absolute improvement of ≥20 points , or 2 in the following: pain, function or patient’s global assessment (all ≥20% relative and ≥10 points

absolute).

The following outcome measures will be used for the responders criteria: subscales pain and hand functioning of the AUSCAN questionnaire, for hand OA, and LEFS and KOOS questionnaires, for function and pain in knee OA, respectively, and patient global assessment on a VAS for both patient groups.

Secondary outcome

- Synovitis, measured by MRI (Knee OA), ultrasound (Hand OA) and hsCRP serum level

- Patient reported outcome measures for pain, function and stiffness (WOMAC-pain, WOMAC-function, WOMAC-stiffness) and quality of life (SF-36)

- Health care use (questionnaire)

- Physical examination of the joints (pain, swollen, bony enlargements, etc.)

Study description

Background summary

OA is the most common form of joint disease and is characterized by an imbalance in breakdown and synthesis of cartilage, bone changes and inflammation of the synovium. The most prevalent affected joints are the knee, hip and hand joints. Pharmaceutical (analgesics) and non-pharmaceutical treatment modalities (education, exercising and weight reduction) are focused on improving self-management and symptom reduction (pain and functional limitations). These treatment modalities are not effective in a large part of the patients. Clinical studies in Germany and Eastern Europe report positive effects of low dose radiotherapy; low dose radiotherapy is a frequently applied treatment modality in those countries. Low dose Radiotherapy can be an interesting alternative for patients with osteoarthritis in the hands and knees in whom non-surgical interventions are insufficiently effective and for whom surgical treatments are not (yet) an option.

This proposal focuses on the potential role of LD-RT, i.e. radiotherapy dosed at 6 Gy in the treatment of OA.

Primary Objective:

To assess the effect of low dose radiotherapy on pain and functioning in hand and knee osteoarthritis.

Secondary Objective(s):

To assess the effect of low dose radiotherapy on signs of inflammatory processes in hand and knee osteoarthritis.

The proposal consists of two sub-studies, both with a randomized, double blind, sham-controlled design; one for hand OA and one for knee OA. Both studies have a similar design, intervention, outcome measurements and time line. Patients with established hand or knee OA, resistant to non-surgical treatment options will be invited to participate in the study by their rheumatologist. After baseline assessments, patients will be randomly allocated to the experimental intervention (LD-RT, 6 fractions in two weeks) or the control intervention (sham RT, 6 times in two weeks). Objective assessments (joint scores and ultrasonography to assess inflammation) at baseline and 14 weeks after baseline will be performed by a blinded assessor. Questionnaires will be collected at baseline and 6, 10, 14 and 26 weeks after baseline.
In this study we aim to include 54 patients with hand OA and 54 patients with knee OA without indication for surgical treatment and after failure of non-surgical treatment options. Patients with hand or knee OA who visited the department of rheumatology of the Sint Maartenskliniek for a standardised, non-surgical treatment regimen, will be invited by letter by their clinician to participate in the study. All patients will be recruited in The Netherlands.

The experimental intervention arm consists of external beam radiotherapy with a total dose of 6 Gy. This total dose is applied in 6 fractions of 1 Gy, spread over 2 weeks, according to the 2002 consensus guidelines for radiation therapy of benign diseases (Micke 2002). Before the first fraction is applied, the exact target locations for RT will be marked by a trained radiotherapy technician, on basis of a CT-scan. The intervention is limited to the index knee in knee OA and to the DIPJ’s, PIPJ’s and thumb base in hand OA.

The total process, including patient instructions and marking of the target location, will be identical for the control intervention arm. However, in this study arm, the radiotherapy device will not be activated, resulting in a sham radiation of 6 times 0 Gy in 2 weeks. All patients will wear head phones playing music during treatment to reduce the risk of unblinding by the sounds associated with the intervention. Both the experimental and the control interventions will be applied at the Department of Radiotherapy of the Radboud Nijmegen Medical Centre.

The primary outcome measure is the percentage of responders according to the 2004 OMERACT-OARSI responder criteria (Pham 2004), 14 weeks after baseline: either improvement in pain or function ≥50% and an absolute improvement of ≥20 points , or 2 in the following: pain, function or patient’s global assessment (all ≥20% relative and ≥10 points absolute).

The following outcome measures will be used for the responders criteria: subscales pain and hand functioning of the AUSCAN questionnaire, for hand OA, and LEFS and KOOS questionnaires, for function and pain in knee OA, respectively, and patient global assessment on a VAS for both patient groups.

Study objective

-Low dose radiotherapy has positive effects on pain and functioning in osteoarthritis of the

hand and knee

-Low dose radiotherapy is effective on reducing inflammatory signs of osteoarthritis of the hand and knee

Study design

Baseline: AUSCAN (hand), LEFS and KOOS (knee), Patient Global Assessment, SF-36 and Health care use questionnaires. MRI-synovitis, hs-CRP serum levels.

Week 6: AUSCAN (hand), LEFS and KOOS (knee), Patient Global Assessment, SF-36 and Health care use questionnaires.

Week 10: AUSCAN (hand), LEFS and KOOS (knee), Patient Global Assessment, SF-36 and Health care use questionnaires.

Week 14: AUSCAN (hand), LEFS and KOOS (knee), Patient Global Assessment, SF-36 and Health care use questionnaires. MRI-synovitis, hs-CRP serum levels. Number of responders according to the 2004 OMERACT-OARSI responder criteria (Pham 2004): either improvement in pain or function ≥50% and an absolute improvement of ≥20 points , or 2 in the following: pain, function or patient's global assessment (all ≥20% relative and ≥10 points absolute).

The following outcome measures will be used for the responders criteria: subscales pain and hand functioning of the AUSCAN questionnaire, for hand OA, and LEFS and KOOS questionnaires, for function and pain in knee OA, respectively, and patient global assessment on a VAS for both patient groups.

Week 26:AUSCAN (hand), LEFS and KOOS (knee), Patient Global Assessment, SF-36 and Health care use questionnaires.

Week 54: AUSCAN (hand), LEFS and KOOS (knee), Patient Global Assessment, SF-36 and Health care use questionnaires.

Intervention

The experimental intervention arm consists of external beam radiotherapy with a total dose of 6 Gy. This total dose is applied in 6 fractions of 1 Gy, spread over 2 weeks, according to the 2002 consensus guidelines for radiation therapy of benign diseases (Micke 2002). Before the first fraction is applied, the exact target locations for RT will be marked by a trained radiotherapy tecnician, based on a CT-scan. The intervention is limited to the index knee in knee OA and to the DIPJ's, PIPJ's and thumb base in hand OA.

The total process, including patient instructions and location marking, will be identical for the control intervention arm. However, in this study arm, the radiotherapy device will not be activated, resulting in a sham radiation of 6 times 0 Gy in 2 weeks. All patients will wear head phones playing music during treatment to reduce the risk of unblinding by the sounds

associated with the intervention. Both the experimental and the control interventions will be applied at the Department of Radiotherapy of the Radboud University Nijmegen Medical Centre.

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Eligibility criteria

Inclusion criteria

Hand OA:

•Hand OA according to the 1990 ACR diagnostic criteria for hand OA (Altman 1990)

•Mean VAS pain during hand activities of both hands > 4 during 15 of the last 30 days.

•Treatment failure of conventional treatment (pain medication and occupational or physical therapy)

•Age ≥50 years

•Able to read, write and sufficiently communicate in Dutch

Knee OA:

•Osteoarthritis in the index knee, according to the ACR classification criteria for symptomatic OA of the knee (Altman 1986)

•Mean VAS pain during activities of the index knee > 4 during 15 of the last 30 days

•Treatment failure of conventional treatment (pain medication and physical therapy)

•Age ≥50 years

•Able to read, write and sufficiently communicate in Dutch

Exclusion criteria

Hand OA:

•Treatment by an occupational or physical therapist in the last 3 months

•Scheduled for surgical treatment of the hands in the next 6 months, or previous surgical treatment of the joints in the hands (eg release of median nerve entrapment or trigger finger correction are allowed)

•Pain of MCPJs and / or wrist being predominant: patients will be asked to name the two most painful joint areas: PIPJs, DIPJs, MCPs, thumb base, wrist. Because radiotherapy will be targeted on the PIPJs, DIPJs and thumb base joint, pain at wrists and MCPJs could interfere with the outcome on pain at treated joint sites.

•Other active rheumatic diseases than OA with possible hand localisation

•Cognitive deficits affecting the scoring process

•Received intramuscular of intra-articular corticosteroid injections in the previous 4 weeks

•Fibromyalgia according to the 2010 ACR diagnostic criteria for fibromyalgia (Wolfe 2011)

•Any other syndrome(s) or condition(s) that could interfere with the assessment of pain

•Severe current psychiatric disorders assessed by physician

•K&L score >3

Knee OA:

Treatment by an occupational or physical therapist in the last 3 months

•Scheduled for surgical treatment of the knees in the next 6 months, or previous surgical treatment of the knee

•VAS pain > 2/10 in the contralateral knee

•VAS pain > 2/10 in one or both hips

•Other rheumatic diseases than OA with possible knee localisation

•Cognitive deficits affecting the scoring process

•Received intramuscular of intra-articular corticosteroid injections in the previous 4 weeks

•Fibromyalgia according to the 2010 ACR diagnostic criteria for fibromyalgia (Wolfe 2011)

•Any other syndrome(s) or condition(s) that could interfere with the assessment of pain

•Severe current psychiatric disorders assessed by physician

•K&L score >3

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2014
Enrollment:	108
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL4451
NTR-old	NTR4574
Other	Dutch Arthritis Foundation : 2014_1_041

Study results