

Effect van lage dosis radiotherapie bij pijn bij milde heupartrose

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24950

Source

NTR

Brief title

Radiotherapy, Osteoarthritis, Pain

Health condition

Patients with Painful, low-grade* osteoarthritis of the hip who present themselves at the orthopedic outpatient clinic of Orbis Medisch Centrum.

Sponsors and support

Primary sponsor: dr E.J.P. Jansen

Orthopedic surgeon

Atrium-Orbis MC

Sittard-Geleen

Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

To determine the effect of LDRT on pain sensation after 1,2,3,6 months in

early osteoarthritis of the hip, measured with a Visual Analogue Scale (VAS), compared to placebo 'sham' irradiation and standard-of-care conservative treatment.

Secondary outcome

- To determine the effect of LDRT on patient reported outcome measures (PROM) including WOMAC and Oxford Hip Score.
- To determine the effect of LDRT on quality of life, assessed with the EuroQoL-5D questionnaire.
- To investigate the relationship between effect of LDRT and level of synovitis, measured through ultrasound, bone scintigraphy and blood BSE level.

Study description

Background summary

Currently, radiotherapy for pain reduction in OA is an accepted and frequently used treatment in Germany and in Central and Eastern European countries. (Seegenschmiedt, 2000; Leer, 2007) In the 1960s and 70s, LDRT was also used for OA in The Netherlands, but it is not commonly practised anymore due to conflicting literature on this topic and fear of tumour induction. Even though some studies show excellent results regarding this treatment, the quality of the available literature is not convincing and level I evidence is still missing. (Seegenschmiedt, 2000 & 2008)

Low-dose radiotherapy (LDRT) is an old but poorly investigated treatment modality for pain related to degenerative joint pathology such as osteoarthritis. It has been shown that low-dose radiotherapy can decrease inflammation activity and can thus possibly reduce local pain sensation. In early osteoarthritis of the hip, synovitis has a prominent role in pain sensation. Therefore, we will investigate the effect of low-dose radiotherapy on pain sensation in patients with mild osteoarthritis of the hip.

Study objective

Our hypothesis is that radiotherapy can achieve a pain-reducing effect of at least 20% after 6 months.

Study design

At baseline and subsequent followup will be after 1, 2, 3 and 6 months.

Intervention

The study design is a prospective, double-blind, randomized trial. We will include 60

patients with early osteoarthritis of the hip, not willing or not able to undergo surgery. The patients will be recruited in the orthopedic clinic of Orbis MC, after which they will be included and randomized. The patients will be randomized into three groups:

- 1: Irradiation (6x1 Gy) plus standard of care (n=24)
- 2: Sham (placebo) irradiation plus standard of care (n=24)
- 3: Standard of care alone (n=12)

Contacts

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Eligibility criteria

Inclusion criteria

- Painful, low-grade* osteoarthritis of the hip
- Above 50 years old
- Synovitis confirmed with ultrasound imaging
- Ability and willingness to follow instructions and to return for follow-up evaluations

*: Kellgren-Lawrence grade I-II

Exclusion criteria

- Patients diagnosed with reumathoid arthritis

- Patients with osseous metastasis
- Patients with rheumatoid factor > 20 kU/l or blood sedimentation rate > 20mm
- Patients with a moderate or severe osteoarthritis grade**
- Patients with a hip/spine dilemma
- Prosthetic implant in the affected joint
- Not able or willing to undergo bone scintigraphy or blood sampling

** : Kellgren-Lawrence grade III-IV

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2015
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion	
Date:	22-01-2015
Application type:	First submission

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	NL4840
NTR-old	NTR4964
Other	NL43876.096.13, CCMO : 13-T-86, METC

Study results

Summary results

NA