The effect of low-dose radiotherapy on pain in mild osteoarthritis of the hip

Published: 21-01-2015
Last updated: 24-04-2024

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Ethical review	Approved WMO
Status	Suspended
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41561

Source
ToetsingOnline

Brief title
Radiotherapy for pain in osteoarthritis of the hip

Condition

- Joint disorders

Synonym
osteoarthritis and hip joint degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Osteoarthritis, Pain, Radiotherapy

Outcome measures

Primary outcome

Objectives

Primary objective.

•To determine the effect of LDRT on pain sensation after 1,2, 3 and 6 months in early osteoarthritis of the hip, measured with a Visual Analogue Scale (VAS)

Secondary outcome

Secondary objectives

•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 through 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

Osteoarthritis (OA) is a degenerative disorder of articular joints leading to a gradual loss of articular cartilage. This disease can give rise to pain, joint effusion, locking phenomena and a limited range of motion. The increase in life expectancy, change in life-style habits as well as a growing number of obese patients lead to a growing number of patients suffering from painful OA. Above the age of 65 years, 17% of the male population and 29% of the female population has some degree of OA. Although it is well known that there is a large discrepancy between radiologic findings and pain, the percentage of

patients suffering from pain increases with the radiologic grade of OA.

Initial management of osteoarthritis is usually conservative. This may include analgesics and non-pharmacological therapy such as weight loss, physical therapy and ambulatory aids. Non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroid injections are considered to be preferred agents for the pharmacological management of OA. However, many of the NSAIDs, both the COX-2 selective inhibitors and the traditional NSAIDs, are associated with a moderately increased risk of cardiovascular events and gastro-intestinal problems. Local treatment with intra-articular injections can be effective, but longer-term benefits have not been confirmed. If conservative treatment fails, surgical options are considered, of which joint arthroplasty is most effective. In the older patient, especially when severe comorbidity is present, surgery may be considered too risky. Therefore effective non-invasive treatment options are urgently needed for patients with a painful OA, who cannot be operated because of their comorbidity, or are not willing to undergo surgery. Furthermore, in early stages of OA, other conservative treatments options are needed to relieve pain, postpone operative intervention and minimize analgesic-related side-effects.

Currently, radiotherapy for pain reduction in OA is an accepted and frequently used treatment in Germany and in Central and Eastern European countries. It is not commonly practised in other parts of the world 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.

Study objective

The main objective of this prospective randomized study is to examine the effect of low-dose radiotherapy on pain sensation in patients with early OA of the hip.

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

Study design

Clinical, prospective, randomized study.

Study burden and risks

Low-dose radiotherapy provides for a low-risk, non-invasive treatment modality for patients with painful osteoarthritis. It could potentially lower the need for medication with its related side-effects, and possible postpone or prevent surgical intervention.

Directly following radiation, the joint might be slightly more painful, but this effect normally disappears in the first weeks after radiation. The reported life-time risk of cancer induction due to LDRT is about 0.2%.

Cancer induction due to radiotherapy
There is ongoing discussion about the risk of cancer induction due to low-dose radiotherapy. Dose distribution in the body is not homogeneous during radiation therapy, which together with the different susceptibilities for radiation-induced carcinogenesis in the different organs exposed, makes it difficult to properly estimate the risk. The concept of *effective dose delivered to tissues* introduced by the International Commission on Radiological Protection (ICRP) contributes to a more accurate estimation of this risk.
The effective radiation dose which is delivered to tissues is dependent on the weighing factors of the tissue.These factors represent the susceptibility of the tissue to radiation. The effective radiaton dose is measured in Sievert (Sv), whilst the overall administered dose is measured in Gray (Gy).

During irradiation of the hip joint, the exposed tissues include bone marrow, bone, skin and muscle. We estimate that the hip joint will consist of at most 3% of the total body tissue. An estimate of the total effective dose of 6 Gy radiotherapy of the hip joint can be calculated as follows:

E = 0.12 (weighing factor red bone marrow) x 6 (6 Gy) x 0.03 (3% of tissue) + 0.01 (weighing factor skin) x 6 x 0.03 + 0.01 (weighing factor bone) x 6 x 0.03 + 0.05 (weighing factor other tissues) x 6 x 0.03 = 34 mSv

This number can be used to make a rough estimation of the risk of cancer induction, specifically the life-time risk of developing a fatal tumour. For the general population, this risk has been set on 5% per Sv. Thus, in the case of 6 Gy radiotherapy, the added life- time risk for developing a fatal tumour would be 0.2%. It needs to be noted that the average time for developing an hematological malignancy is between 5 and 10 years. For solid tumours, this time is around 15-20 years. We will estimate that our patient population will have an average age of around 70 years, which makes the risk of tumour induction by 6 Gy radiotherapy extremely low.

For reference, the annual background radiation in The Netherlands is about 2 mSv whilst a trans-Atlantic flight from Amsterdam to New York amounts to about 0.04 mSv. For further reference, patients with head/neck carcinomas are irradiated with 70 Gy (35 fractions), lung carcinomas up to 69 Gy (42 fractions) and oesophagus carcinomas up to 41.4 - 50.4 Gy.

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

Painful, low-grade osteoarthritis of the hip (Kellgren-Lawrence graad I-II)
Above 50 years old
Synovitis confirmed with ultrasound imaging
Ability and willingness to follow instructions and to return for follow-up evaluations

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 (Kellgren-Lawrence graad III-IV)

Patients with a hip/spine dilemma
Prostethic implant in the affected joint
Not able or willing to undergo bone scintigraphy or blood sampling

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	04-02-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	21-01-2015
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL43876.096.13