Towards the primary prevention of hip OA - pilot study

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

Summary

ID

NL-OMON57090

Source
ToetsingOnline

Brief title
OA Pearl 1

Condition

- Joint disorders

Synonym
osteoarthritis of hip

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Dutch Arthritis Society (ReumaNederland)

Intervention

Keyword: OA hip, pilot study, prevention

Outcome measures

Primary outcome

The primary outcome for the current pilot will be the feasibility of the proposed recruitment strategies. We deem the pilot to be feasible when out of a maximum of 150 participants, 30 (20%) participants are eligible after the physical examination and radiography to participate in the proposed preventive trial.

Secondary outcome

The secondary study parameters/endpoints (the feasibility for the willingness of potential participants) will be met if >=75% of the eligible participants (i.e., with cam morphology and no hip OA on radiography) is willing to participate in the future prevention trial.

Other study parameters:

Hip MR images, obtained in 30 participants only, will be assessed using the semi-quantitative SHOMRI scoring system.

Furthermore, for each recruitment strategy, we will determine:

1. The efforts; the costs for personnel and material.

2. The outcome; the number of individuals contacting the research center.

3. The effectiveness of registration; the percentage of individuals fulfilling the telephonic selection criteria.

4. The effectiveness of screening; the percentage of individuals with cam and

no radiographic hip OA.

Study description

Background summary

Osteoarthritis (OA) is already one of the most common and by far the fastest growing disease in the Netherlands. Despite the enormous severity of the symptoms of osteoarthritis, we can only offer patients with osteoarthritis modestly effective treatments for their complaints.

Treatments to cure osteoarthritis have not yet been very successful, but have mainly been investigated in patients where the joint tissue is already significantly damaged and hardly specific to the type of osteoarthritis.
With such a common, disabling and incurable condition, our efforts should be much more focused on its primary prevention.

The hip is the second most commonly affected joint (after the knee) and is responsible for the highest rate of disability. Several modifiable risk factors, mainly related to hip shape, have been previously identified and therefore have great potential for preventive options.

With our future preventive hip OA trial we will assess the effects of exercise therapy in individuals at high-risk for hip OA development due to the presence of cam morphology. An important outcome measure in the future preventive trial will be the progression of structural abnormalities on MR images, such as bone marrow lesions, cartilage defects, labral tears, osteophytes, and inflammation.

The theoretic basis of primary prevention of hip OA might sound simple, appealing, and feasible: preventing the onset of OA among subjects without, but at high risk for OA. Nevertheless, to realize this, there are many challenges.

Two challenges will be studied in this pilot study.

Challenge #1; Identify treatment goals
We have previously shown that hip morphology (e.g. a cam deviation) is one of the largest risk factors for the development of hip osteoarthritis.
Therefore, preventing the development of osteoarthritis in individuals with morphological risk factors appears to be a promising strategy.

One of the major risk factors for cam morphology is sport participation during the last growth spurt.
Especially for sport participation in high loading sports, such as soccer, basketball, hockey, and jumping sports.

Traditionally, these sports were male dominant sports and hence reports of cam prevalence showed higher prevalence among men. However, given the increase in sport participation in girls over the last decades, increasing prevalence is reported in women as well.

Challenge #2; Designing the intervention
When a reliable individualized estimation of hip OA risk can be made, high risk subpopulations can be identified, which probably increases the likelihood of adherence to a certain preventive strategy.

Interestingly, a small recent RCT showed a significant increase in cartilage quality and clinically relevant effects on hip joint symptoms after a conservative physiotherapist-led hip therapy program among patients with cam morphology .

Given these results and the knowledge on the high risk of hip OA development in individuals with cam morphology, we have identified the potential treatment population and a potential intervention for our future preventive hip OA trial.

Challenge #3; Measuring the effect
Both OA symptoms and structural features of OA develop gradually. Therefore, when evaluating potential outcomes for preventive trials in OA, the annual incidence rate of the outcome is an important feature for the feasibility of such a trial.

Study objective

The primary objective of the current pilot study will be to assess the feasibility of participant selection methods to identify individuals with cam morphology free of hip OA.

Secondary objectives include
a) the evaluation of the willingness of potential participants to participate in a preventive trial and to undergo the intervention, and

b) to gain insight into structural features of early stages of hip OA on MRI of potential participants, to design relevant outcome measures.

Study design

Study design

The current study will be an observational feasibility pilot. For recruitment, we will compare three strategies:

#1) Recruitment through GP practices.

We will recruit three GP practices from our regional network in the greater Rotterdam region. Within these practices, all registered patients aged 18-55 years without a diagnosis of hip OA will be sent an information letter.
Those who report participation in high loading sports when aged 10 through 16 for >=2 days/week for >=1 year and are interested to participate will be asked to contact the research center.

In addition, we will post advertisements in local media in the Rotterdam area (strategy #2), such as De Havenloods, AD Rotterdam, RTV Rijnmond, but also through the social media channels of Erasmus MC and our Department.
The advertisement will call for individuals who participated in high loading sports when aged 10 through 16 for >=2 days/week for >=1 year and who are interested to join our research on OA prevention, to reach out to the research center.

For recruitment strategy #3, we will collaborate with our stakeholders at national sport associations within our network (e.g., Golazo Sport (running), National Hiking Association, and KNLTB (tennis)). As done in previous collaborations, these associations will reach out to their members in the Rotterdam area and ask them to spread our advertisement (see strategy #2) with their supporters. As for strategy #2, individuals interested to join the study are asked to contact the research center.

With all individuals that contact the research center, we will perform a telephonic screening to ascertain the absence of clinical hip OA (using NICE criteria; age >=45 years and activity-related hip joint pain and no or <=30 minutes of morning stiffness in the hip joint), the fulfilment of the inclusion criteria, and through which means they were informed about this study.

Individuals without clinical hip OA, that do fulfil our recruitment criteria will be invited
a) to complete an online questionnaire (±15 minutes) to obtain subjects* characteristics, detailed sport participation during childhood, current hip symptoms and functional limitations, and other risk factors for cam morphology/hip OA (e.g., occupational loading) and

b) for a physical examination (±20 minutes) and radiography of their hips at the research center.
During this visit, a physical examination of both hip joints will take place.
By subsequently obtaining radiography of all potential candidates, we will be able to evaluate the efficiency of our recruitment strategies, regarding the presence of cam morphology and the absence of any radiographic hip OA (i.e. KL-grade=0).

After completion of the physical examination and radiographic assessment, individuals with cam and no radiographic hip osteoarthritis in >=1 hip will receive information material on the design of the future preventive RCT, along

with a Patient Information Folder. Individuals will be asked to carefully read all information and sign informed consent if they are willing to undergo an MRI and participate in a future preventive trial. After signing informed consent, participants will receive the online questionnaire (approximately 5 minutes, in which we assess their attitudes and beliefs regarding their willingness to follow a preventive exercise therapy program), and they will be invited for a multi-sequential MRI of the hip.

Study burden and risks

The burden to participants will equal
- the time spend to complete the online questionnaire,
- to travel to the research center,
- to undergo physical examination, and for completing the radiography

for subjects forfilling requirements{
- time to spend to complete the additioal questionnaire
- MRI (for those eligible for MRI).

Risks for participation are limited to the <0.1 mSv radiation dose for two hip radiographs.

There is no direct benefit of participation, but with participating in this pilot study, participants contribute to an important step in osteoarthritis prevention science.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Aged 18-55 years
- Self-reported participation in high loading sports when aged 10 through 16 for >=2 days/week for >=1 year
- Willing to visit the research center for physical examination and radiography
- Master the Dutch language

Exclusion criteria

- Medical diagnosis of hip OA by their GP
- Meeting the NICE criteria for hip OA at telephone screening
- Pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-09-2024
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	05-11-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL85694.078.24