PRevention of knee Osteoarthritis in Overweight Females (PROOF); long-term follow-up

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

Summary

ID

NL-OMON41125

Source
ToetsingOnline

Brief title
PROOF study

Condition

- Joint disorders

Synonym
knee osteoarthritis, wear and tear

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Uit een European Commission 7th Framework Programme Project

Intervention

Keyword: Knee osteoarthritis, Overweight, Prevention

Outcome measures

Primary outcome

The primary outcome measure is the incidence of clinical knee osteoarthritis

according to the 'clinical and radiologic ACR-criteria'

Secondary outcome

The secondary outcome measures are:

- incidence of radiologic knee osteoarthritis (K&L >= 2)

- incidence of joint space narrowing (JSN >= 1.0 mm)

- progression of MRI features of knee osteoarthritis (MOAKS features)

- WOMAC pain

- WOMAC function

- Quality of life

- degenerative biomarkers in blood/urine

Study description

Background summary

The current project is a follow-up of an in 2012 completed randomized controlled trial on the effects of a lifestyle intervention aimed at weight loss and a placebo-controlled glucosamine sulphate intervention in middle-aged overweight women. A total of 407 women between 50 and 60 years participated in this study. After an average follow-up of 2.5 years, there was a small but significant decrease in body weight in the intervention group of the life style intervention. It this relatively short follow-up period, only a positive trend of the lifestyle intervention on the development of knee osteoarthritis was found. There was no preventive effect of the glucosamine sulphate demonstrated. However, there appeared to be a negative effect of the glucosmaine sulphate on

the number of people with elevated blood sugar after 30 months.
International literature dictates that in order to evaluate the effects of weight reduction on health factors a minimum follow-up period of four years is necessary. That is why we want to approach all participants of the original trial now, after an average of 6.5 years, again. Moreover, this enables us to evaluate the intervention effects on the development of clinical and radiographic knee OA seperately, whereas these were combined for feasibility reasons in the original trial. 95% of all participants who have been to the final measurement of the original trial has given permission to be approached for a possible continuation of the trial.

Study objective

The aim of the current project is to evaluate the long-term effects of a) a pragmatic lifestyle intervention aimed at weight loss and b) a 30-month placebo-controlled intervention with glucosamine sulphate on the development of knee osteoarthritis after 6.5 years in overweight women.

Study design

All women who have given their consent to be contacted again, will be written to ask for their participation. By phone, inclusion and exclusion criteria will be checked, any questions will be answered and after consent of the subject an appointment for a single measurement will be made.
During this measurement, a questionnaire and a physical examination will be administered, an X-ray and MRI of both knees will be made and a blood sample will be drawn by vena punction. After these measurements (± 90 minutes), the participation of the subject is directly ended; there is no intervention tested and there will be no follow-up.

Study burden and risks

The measurements are the same as performed at the final measurement of the original trial, so all participants will be familiar with the burden of participation. The burden of participation and the risks of the measurements to be carried out are very low. It is only a single measurement of ± 90 minutes, with only a slightly increased risk in making the X-rays (radiation) and obtaining a sample of blood through the vena puncture.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Was participant in original trial. 2) Gave informed consent to be contacted for long-term follow-up at final measurements of the original trial.

Exclusion criteria

No criteria excluding individuals who fulfill the inclusion criteria.
Subjects with contra-indications for MRI will only be excluded for MRI measurements and subjects with bi-lateral total knee replacement will only be excluded for MRI and radiography.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	330
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2014
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
Other	ISRTCN 42823086
CCMO	NL48772.078.14