Prevention of Osteoarthritis in Overweight Females.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24692

Source
Nationaal Trial Register

Brief title
PROOF study.

Health condition

Osteoarthritis of the knee

Sponsors and support

Source(s) of monetary or material Support: ZonMw - the Netherlands Organisation for Health Research and Development

Intervention

Outcome measures

Primary outcome

1. Percentage participants per group showing a reduction of 5kg and/or 5% decrease at one year follow-up compared to baseline weight;

2. Percentage women compliant to the interventions in the study;

3. Percentage lost to follow-up after one year;

4. Percentage participating person of eligible persons.

Secondary outcome

1. Difference in intermediate outcomes between intervention group A and control group A at one year follow-up;

2. Difference in intermediate outcomes between intervention group B and control group B at one year follow-up;

3. Change and variation in change in intermediate outcomes between baseline and one year follow-up.

Study description

Background summary

The past decades, world wide research identified the major risk factors for developing osteoarthritis (OA) of the knee. The next important step in osteoarthritis research, also based on recent developments on intermediate outcome measures in OA, is to test preventive strategies in high risk groups.
Overweight is the major modifiable risk factor in knee OA. Overweight most often is caused by an unbalanced food intake in relation to physical activity, a way of life which is hard to change. To accomplish any change in such behavior, a tailor made intervention with diet and physical activity is the most successful. However, an intervention with glucosamine, a product with growing scientific evidence for its chondroprotective actions, is probably much more easy and feasible then the above mentioned intervention.

In the present feasibility study we will test the feasibility of both interventions, and the procedures as well as the potential value of the intermediate outcome measures. The study population will comprise a high risk group for knee OA of 100 overweight women aged 50-60 years who not yet have consulted for pain in the knee. In a randomized controlled trial with factorial design half of the women will be randomized to the tailor made intervention to reduce weight; the other half will not receive this intervention. Secondly, in
both groups half of them will be randomized to receive glucosamine while the other half will receive a placebo. Because OA is a gradually ongoing process and radiological OA features only are late
derivatives of the processes in the joint, we will also measure intermediate outcomes (osteoarthrotic features measured on MRI, bone and collagen markers), giving a more direct insight in ongoing processes in and around the joint.

In the feasibility study there is a one year follow-up to judge the accomplished weight

reduction, the compliance to both interventions, the intermediate outcomes, and the procedures.

When the feasibility study is judged successful according to predefined criteria, the status of the study can be upgraded and patients from the feasibility study will continue to be participants of the full-scale
preventive trial (with 400 participants and two and a half year follow-up).

Study objective

The present study is a feasibility study. In this study we will test the feasibility of the procedures used, the compliance to the interventions, and the usefulness of intermediate outcome measures in a specific high risk group. If the results of this feasibility are satisfactory, the project will be upgraded into a full scale preventive trial.

Study design

N/A

Intervention

Intervention A:

a tailor-made intervention to reduce weight under direction of dieticians of homecare Rotterdam for one year. The control group will not receive this active intervention to reduce weight.

Intervention B:

daily suppletion with glucosamine sulphate (1500 mg/day) for one year. The control group will receive a placebo.

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Eligibility criteria

Inclusion criteria

Women aged 50-60 years with overweight (BMI of 27 or more).

Exclusion criteria

1. Knee OA;

2. Knee pain indicating knee OA;

3. Radiological signs indicating knee OA (Kellgren-Lawrence index of 2 or more);

4. Positive for knee OA according to the ACR criteria for knee OA;

5. Presence of severe co-morbidity;

6. Pacemaker;

7. Already use of glucosaminesulphate;

8. Not being able to communicate in the Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2005
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	11-05-2006
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	NL620
NTR-old	NTR679
Other	: N/A
ISRCTN	ISRCTN42823086

Study results

Summary results
N/A