Prevention of Osteoarthritis in Overweight Females.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24692

Bron
NTR

Verkorte titel
PROOF study.

Aandoening

Osteoarthritis of the knee

Ondersteuning

Overige ondersteuning: ZonMw - the Netherlands Organisation for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2005
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	11-05-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL620
NTR-old	NTR679
Ander register	: N/A
ISRCTN	ISRCTN42823086

Resultaten

Samenvatting resultaten
N/A