The effect of high-resistance muscle strength training and vitamin D supplementation in persons with knee osteoarthritis

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29469

Source
Nationaal Trial Register

Brief title
VIDEX

Health condition

Knee joint, Osteoarthritis, Muscle strength, Vitamin D
Knie. Artrose, Spierkracht, Vitamine D

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Reumafonds

Intervention

Outcome measures

Primary outcome

Muscle strength of the knee extensors and knee flexors.

Secondary outcome

Knee pain, activity limitations (self-report and performance based), self-reported knee instability/falls and fractures, proprioception, inflammatory markers (i.e. C-reactive protein and Erythrocyte Sedimentation Rate), and depressive and anxious mood. Global perceived effect.

Study description

Background summary

Background

As there is currently no cure for OA, conservative treatment is the cornerstone of OA management. Muscle strengthening in particular is a key-target in the conservative treatment of knee OA. In all major international treatment guidelines, exercise therapy (with a dominant role for muscle strengthening) is recommended. However, the optimal training intensity of muscle strengthening exercises in knee OA is not known to date and this is important to maximize patient outcomes from exercise therapy. Based on research in non-OA populations it is expected that high-resistance strength training is more effective than low-resistance strength training to improve muscle strength, without causing serious side effects.

Also, it has been hypothesized that vitamin D supplementation could enhance the effects of exercise therapy on muscle strength, since low serum 25-hydroxy (OH) vitamin D level, which is common in older adults, is associated with impaired muscle cell function. In healthy subjects, indications for a beneficial effect of vitamin D supplementation plus exercise on muscle strength have been found. To improve the effectiveness of strength training in patients with knee OA vitamin D supplementation has the potential to be a useful adjunct.

Aims

To determine (1) whether high-resistance strength training (70-80% of one-repetition maximum (1RM)) is more effective in improving muscle strength compared to low-resistance strength training (40-50% of 1RM) in patients with knee osteoarthritis and (2) whether vitamin D supplementation enhances the effect of muscle strength training on muscle strength in knee OA patients with vitamin D deficiency.

The ultimate goal of the intervention study is to optimize strength training in knee OA, thereby increasing the beneficial effect on pain and activity limitations.

Study design

Patients with knee OA will be randomized into two groups: 1) high resistance strength training 2) low resistance strength training. Patients with knee OA and vitamin D deficiency will be randomized into four groups:1) high resistance strength training and vitamin D supplementation, 2) high resistance strength training and placebo, 3) low resistance training and vitamin D supplementation, 4) low resistance strength training and placebo. The power calculation showed that a total of 220 patients are needed. When controlling for repeated measures, the power calculation showed that a total of 178 patients are needed.

Intervention

1) In patients with knee OA the total intervention period will be 3 months. In these 3 months, patients will receive a strength training program, including exercises that are primarily aimed at improving quadriceps and hamstring strength. Both the high-resistance strength training group and the low-resistance strength training group will undergo 3 training sessions per week. In the high-resistance group exercises will be performed with a load of 70-80% of 1 repetition-maximum (1RM) compared to a load of 40-50% of 1RM in the low-resistance group.

2) In patients with knee OA and vitamin D deficiencyT the total intervention period will be 6 months. In the first 3 months, vitamin D tablets (1200IU daily) or placebo tablets will be taken in order to increase the 25(OH) vitamin D level (in case of vitamin D tablets). In the second 3 months, patients will additionally receive a strength training program, including exercises that are primarily aimed at improving quadriceps and hamstrings strength. Both the high-resistance strength training group and the low-resistance strength training group will undergo 3 training sessions per week. In the high-resistance group exercises will be performed with a load of 70-80% of 1 repetition-maximum (1RM) compared to a load of 40-50% of 1RM in the low-resistance group.

Measurements

Primary outcome measure: upper leg muscle strength. Secondary outcome measures: knee pain, activity limitations, knee instability/falls and fractures, proprioception, inflammatory factors, and depressive and anxious mood. Other measurements: socio-demographic variables, serum 25-hydroxyvitamin D level, health care and medication use, comorbidity, knee alignment, physical activity, body mass index (BMI), compliance and adherence, and side effects.

1)In patients with knee OA measurements will be performed at baseline (start of strength training), at 3 months (post-intervention), at 9months (6 months post-intervention).

2) In patients with knee OA and vitamin D deficiency measurements will be performed at baseline (start of vitamin D supplementation or placebo), at 3 months (start of strength training), at 6 months (post-intervention), and at 12 months (6 months post-intervention).

Intention-to-treat analyses using longitudinal data analyses will focus on establishing the effect of high-resistance relative to low-resistance training and the effect of vitamin D supplementation versus placebo.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Potential participants will be screened with an internet-based (or postal if applicable) questionnaire and by telephone, followed by a screening visit (short physical examination, questionnaire and blood draw). If they pass the screening visit they will be invited to come to Reade for a visit with the rehabilitation physician and rheumatologist for diagnosis and final decision on eligibility. Participants with knee OA will be measured three times: at baseline, after 3 and9 months. Participants with knee OA and vitamin D deficiency will be measured four times: at baseline, after 3, and 9 months. Participants have to complete questionnaires and perform physical performance tests, and blood and urine will be collected.

The intervention period will be 3 months in patients with knee OA. In the first 3 months, patients will receive a strength training program. The intervention period will be 6 months in patients with knee OA and vitamin D deficiency.
In the first 3 months, vitamin D tablets (1200IU daily) or placebo tablets will be taken. In the second 3 months, patients will additionally receive a strength training program.. Strength training is an effective and recommended treatment in patients with knee OA. Risks are minimal, due to supervision of experienced physical therapists and wide experience of the research group in conducting exercise trials in knee OA. The risk of the vitamin D treatment is negligible

Study objective

1. High-resistance strength training leads to greater improvements in muscle strength (primary outcome), pain, activity limitations, self-reported knee-instability, falls and fractures, markers for inflammation and depression and anxiety (secondary outcomes) compared to low-resistance strength training in patients with knee osteoarthritis (OA).

2. Vitamin D supplementation in combination with strength training leads to greater improvements in muscle strength (primary outcome), pain, activity limitations, self-reported knee-instability, falls and fractures , markers for inflammation and depression and anxiety (secondary outcomes) compared to placebo in combination with strength training in patients with knee osteoarthritis (OA) and vitamin D deficiency.

Study design

1)Baseline, 3 months and 9 months in patients with knee OA. 2)Baseline, 3 months, 6 months and 12 months in patients with knee osteoarthritis and vitamin D deficiency.

Intervention

High-resistance strength training or Low resistance strength training in patients with knee OA.

Vitamin D3 1200IU per Day or Placebo and high-resistance strength training or low resistance strength training in patients with knee OA and vitamin D deficiency.

Contacts

Public
Amsterdam Rehabilitation Research Center | Reade, Department of Rehabilitation Medicine
VU University Medical Center
Dr. Jan van Breemenstraat 2, PO 58271

M. Leeden, van der
Amsterdam 1040 HG
The Netherlands
0031-205896291
Scientific
Amsterdam Rehabilitation Research Center | Reade, Department of Rehabilitation Medicine
VU University Medical Center
Dr. Jan van Breemenstraat 2, PO 58271

M. Leeden, van der
Amsterdam 1040 HG
The Netherlands
0031-205896291

Eligibility criteria

Inclusion criteria

-Knee pain and at least 2 of the following 5 items: morning stiffness < 30 minutes, crepitations, bone sensitivity, bony enlargement of the joint margin, no palpable warmth

-Age > 55 and < 80 years

-Vitamin D deficiency: 25(OH)D level >15nmol/L and <50 nmol/L (in winter) or <70nmol/L (in summer)

29-apr-2018 Addendum: Per March of 2015 patients with knee OA without vitamin D deficiency are also included

Exclusion criteria

-Other forms of arthritis than OA (e.g. crystal arthropathy, septic arthritis, spondylarthropathy) identified by radiography and/or blood- and urine samples

-Absolute contra-indication for exercise therapy/strength training: resting systolic blood pressure of >200mgHG or diastolic blood pressure of >115 mgHG, acute myocardial infarction within the last 3 months, chest pain at rest/ before exercise, other severe cardiac diseases (e.g. present inflammations, symptomatic aortic stenosis, sever cardiac arrhythmias)

-Inability to perform strength training program due to severe co-morbidity

-Psychoneuroticism (SCL90>200)

-Total knee arthroplasty (TKA) or TKA scheduled for upcoming year

-Supervised strength training program > 30 minutes/week in past 3 months

-Use of vitamin D supplements >800 IU daily

-Diagnosed with hypercalcemia, hyperparathyroidism or sarcoidosis

-Living in a nursing home

-Inability to be scheduled for therapy

-Insufficient comprehension of Dutch language

-No informed consent

Study design

Design

Study type: Interventional

Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-05-2014
Enrollment:	178
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-05-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44546
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4475
NTR-old	NTR4608
CCMO	NL47786.048.14
OMON	NL-OMON44546

Study results