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

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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) and (2) whether vitamin D...

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

Summary

ID

NL-OMON44546

Source
ToetsingOnline

Brief title
VitD-EX

Condition

- Joint disorders

Synonym
arthrosis deformans, cartilage wear

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut

Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: exercise therapy, knee osteoarthritis, muscle strength, vitamin D

Outcome measures

Primary outcome

Muscle strength of quadriceps and hamstrings (isokinetic test)

Secondary outcome

Knee pain, activity limitations (self-reported and performance-based), knee

instability/falls and fractures (self-reported), proprioception (test),

inflammatory factors in blood, and depressive and anxious mood (self-reported).

Global perceived effect.

Study description

Background summary

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.

Study objective

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) 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

We will conduct a randomized controlled trial with a 2x2 factorial design (n=220). Participants will be randomized into four groups: 1) high resistance strength training and vitamin D3 supplementation, 2) high resistance strength training and placebo, 3) low resistance strength training and vitamin D supplementation, 4) low resistance strength training and placebo. 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).

Addendum:
In addition, 68 knee OA patients with normal vitamin D levels will be included in order to study the effect of high versus low resistance strength training. The larger sample size (n=288) will lead to more statistical power (0.90). Patients with normal vitamin D levels will be randomized into either high or low resistance training, without supplementation with vitamin D or placebo. These patients will have 3 measurement points instead of 4 measurement points: measurements on T1 will be their baseline measurement, as they will start with resistance training without a previous period of supplementation.

Intervention

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 exercise 3 times per week (2 supervised sessions at Reade and 1 home exercise program). 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.

Study burden and risks

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 will be measured four times: at baseline, after 3, 6 and 12 months. Participants have to complete questionnaires and perform physical performance tests and blood and urine will be collected.
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 the second 3 months, patients will additionally receive a strength training program. The risk of the vitamin D treatment is negligible. 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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);In addition, 68 knee OA patients with normal vitamin D levels will be included in order to study the effect of high versus low resistance strength training. The larger sample size (n=288) will lead to more statistical power. Patients with normal vitamin D levels will be randomized into either high or low resistance training, without supplementation with vitamin D or placebo.

Exclusion criteria

- Other forms of arthritis than OA
- Absolute contra-indication for exercise therapy/strength training
- Inability to perform strength training program due to severe comorbidity
- Use of vitamin D supplements >800 IU daily
- Living in a nursing home

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2014
Enrollment:	288
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Devaron
Generic name:	Vitamine D3
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	24-02-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	20-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	16-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	18-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	11-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29469
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2014-000047-33-NL
CCMO	NL47786.048.14
OMON	NL-OMON29469