Additional effect of hydrolysed collagen/vitamin C in exercise treatment for Patellar Tendinopathy (Jumper*s knee); a randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON52228

Source
ToetsingOnline

Brief title
the JUMPFOOD study

Condition

- Tendon, ligament and cartilage disorders

Synonym
or Jumpersknee, Patellar Tendinopathy

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei

Source(s) of monetary or material Support: Ministerie van OC&W,Rousselot,ZGV Research fonds

Intervention

Keyword: Gelatin, Hydrolysed collagen, Patellar Tendinopathy, Progressive tendon loading therapy

Outcome measures

Primary outcome

The primary outcome measure is the change over time in the Dutch version of the VISA-P score. This simple, validated, reliable and injury-specific questionnaire assesses the severity of patellar tendinopathy and is sensitive to small changes in symptoms. It is specifically designed for patellar tendinopathy, assessing pain, symptoms, simple function test and ability to participate in tendon-loading sports [1]. A VISA-P score of 100 indicates no pain, maximum function and maximum ability to participate in sports. The score decreases with increasing severity of PT symptoms. The VISA-P questionnaire will be administered at baseline and after 24 weeks of follow-up. The primary outcome measure is the difference between intervention and placebo in difference score between t=24 and t=0.

Secondary outcome

Secondary outcomes will include: Pain during functional tests, advanced imaging methods and tendon structure and stiffness measurements (ultrasound, UTC, Myoton), blood levels of amino acids and inflammatory markers measured in blood, and dietary habits, that will all be measured at baseline, at 12 weeks and at 24 weeks of follow-up. In addition, data on the compliance with the exercise program and supplement intake, training and competition load will be

collected weekly using an online questionnaire.

Study description

Background summary

Patellar tendinopathy (PT) is a tendon overuse injury with high prevalence rates in elite and recreational athletes. PT sometimes results in a prolonged absence from sport participation, hampering individuals to achieve their desired performance levels and to benefit from the health related effects of sports participation. Many treatment options are used but management of PT remains challenging. Current treatment involves progressive education, load management and tendon loading exercises (PTLE). Recent studies have shown that nutrition can positively affect collagen synthesis in musculoskeletal tissues. A study showed that supplementing 15g of gelatine combined with 50mg of Vitamin C, 1 hour before loading exercises, resulted in an increase in whole body collagen synthesis and increased mechanics and collagen content of human engineered ligaments. However the effectiveness of oral supplementation of hydrolysed collagen in combination with vitamin C in athletes with PT has not been studied in a randomized controlled trial yet.

Study objective

The primary aim of this RCT is to evaluate whether the use of oral supplementation of hydrolysed collagen/vitamin C in addition to usual care (education, load management and PTLE) is superior to usual care and placebo on VISA-P score after 24 weeks for athletes with PT. The secondary aim of this RCT is to evaluate whether the use of oral supplementation of hydrolysed collagen/vitamin C in addition to usual care (education, load management and PTLE) is superior to usual care and placebo on other clinical outcome parameters, functional tests and tendon structure after 12 and 24 weeks for athletes with PT.

Study design

The JUMPFOOD-study is a double blinded, 2-armed randomized placebo controlled trial which investigates the effectiveness of oral supplementation of hydrolysed collagen and vitamin C combined with progressive tendon loading exercise compared to only progressive tendon loading exercises in athletes with PT.

Intervention

The intervention consists of a nutritional supplement with 10g hydrolysed

collagen and 40 mg vitamin C, in comparison to a placebo supplement consisting of maltodextrin. All participants in both groups will receive education, load management advices and a criteria-based PTLE consisting of 4 stages within the limits of pain during 24-weeks, until full recovery. This (training) intervention has recently been proven to be superior to eccentric training. Participants will be randomly assigned to receive either the nutritional supplement hydrolysed collagen/vitamin C (intervention) or a placebo supplement.

Study burden and risks

The time investment of participation consists of following the exercise program 3 times a week during the entire 24-week study period, and of completing a total of 4 hospital visits for inclusion, at baseline, and at follow-up at 12 and 24 weeks. Both groups are expected to benefit from the PTLE exercise therapy as this has recently been demonstrated in a RCT. Participants have to consume the nutritional supplement or placebo supplement daily during the entire study period. The nutritional supplement contains hydrolysed collagen and vitamin C. Too much vitamin C will leave the body via urine and causes no health risks. Collagen is also present in normal food products and is not known to cause any problems. During test days, ultrasounds will be performed without contrast agents, so risks are very small. Blood withdrawals can lead to bruises, but changes are small. Filling in the questionnaires during the study period takes some time but these questionnaires are not psychologically demanding. All potential participants will be examined by an experienced sports physician and additional imaging will be performed to exclude other diagnoses and increase the likelihood of the diagnosis PT, without additional healthcare costs.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

- Signed informed consent.
- Age 16 - 40 years old
- History of focal knee pain in patellar tendon or its patellar or tibial insertion in association with training and/or competition.
- Current symptom duration of at least 12 weeks.
- Sports participation at least once a week for at least one year.
- Palpation tenderness to the corresponding painful area on the patellar tendon.
- Focal patellar tendon pain during patellar tendon loading pain provocation test (single leg decline squat and/or single leg jump squat)
- Victorian Institute of Sports Assessment (VISA-P) score < 80 out of 100 points.
- Willing to take (non-vegetarian) nutritional supplements.
- Willing and able to perform the PTLE program.

Exclusion criteria

- Known presence of inflammatory joint diseases (e.g. spondylarthropathy, gout or rheumatoid arthritis) or familial hypercholesterolaemia.
- Signs or symptoms of other coexisting knee pathology on physical examination (such as joint effusion and joint line tenderness) or additional diagnostics (Chondral lesion of the patella or trochlea on MRI or prepatellar bursitis on US).
- Daily use of drugs with a putative effect on the patellar tendon in the preceding year (e.g. fluoroquinolones and statins).
- Having had a patellar tendon surgery.
- Having had a knee surgery without full recovery.
- Previous patellar tendon rupture of the index knee.

- Local injection therapy with corticosteroids, other drugs, blood, platelet rich plasma or stem cells in the preceding 12 months.
- Acute knee or patellar tendon injuries (other than PT).
- Participation in other concomitant treatment programs.
- Participation in other research projects during participation of the JUMPFOOD study.
- Already using (hydrolysed) collagen supplementation.
- Giving blood donation in a period of two months prior to each test day.
- Being pregnant or wish to become pregnant in the upcoming year.
- Alcohol consumption for men >21 units/week and >4/day; for women >14 units/week and >3/day.
- Abuse of hard drugs.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-05-2023
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO

Date:	22-09-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL79100.081.21 in register.clinicaltrials.gov
CCMO	NL79100.091.22