

Topical nitroglycerin treatment of patellar tendinopathy. A randomized, double-blind, placebo-controlled trial.

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The objective of this randomised, placebo-controlled trial is to compare a combination of eccentric training and nitroglycerin patches with a combination of eccentric training and placebo patches.

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

Summary

ID

NL-OMON33847

Source

ToetsingOnline

Brief title

Topical nitroglycerin treatment of patellar tendinopathy

Condition

- Tendon, ligament and cartilage disorders

Synonym

jumpers knee, patella tendinopathy

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden

Source(s) of monetary or material Support: Ministerie van OC&W, Landsteiner Instituut

Intervention

Keyword: eccentric, jumpers knee, nitroglycerin, patellar tendinopathy

Outcome measures

Primary outcome

VISA-P score

Secondary outcome

VAS score during sports, patients satisfaction, Tegner Score and time to return to sports.

Study description

Background summary

Patellar tendinopathy is a frequent injury in sporting people. Unfortunately, there are no clear strategies for treatment yet. Also there is no therapy with satisfactory results. The etiology of patellar tendinopathy is not totally clear yet and it is very important that we can offer a good treatment strategy to our patients. Recent clinical investigation revealed good results of eccentric training in these patients. Nitroglycerin patches gave some good results in treatment of other kinds of tendon injuries. Probably this is the result of stimulating the production of collagen by nitro oxid.

Study objective

The objective of this randomised, placebo-controlled trial is to compare a combination of eccentric training and nitroglycerin patches with a combination of eccentric training and placebo patches.

Study design

This randomised trial is double-blind. Each patient will receive a patch, but half of them is a placebo one. Eccentric training will also be instructed by every patient. Patients will be examined following a standardized procedure. The investigator is not aware about which kind of therapy the patient is receiving.

Intervention

Eccentric training during 12 weeks. The exercises have to be done two times a day in 3 series of 15 repetitions for everyday of the week.

De nitroglycerin patches or placebo patches have to be applicated each day at the patellar tendon.

Study burden and risks

Everyday eccentric training with a VAS score of 4-5 on a scale of 0 to 10, which takes 10 minutes a day.

Applicate everyday a patch at the patellar region.

There are no risks.

Contacts

Public

Medisch Centrum Haaglanden

Burgemeester Banninglaan 1
2262 BA Leidschendam
NL

Scientific

Medisch Centrum Haaglanden

Burgemeester Banninglaan 1
2262 BA Leidschendam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- age 18 to 40 years
- pain of patellar tendon at least for three months and with a maximum of two years
- pain of patellar tendon during and/or after doing sports
- VISA-P < 80
- pain of patellar tendon during palpation

Exclusion criteria

- clinically suspect of other knee pathology
- knee operation or knee injection in history
- patient did eccentric exercises for the knee before
- hypersensitive for the use of nitrates
- pregnancy
- use of medication which influence the blood pressure, like anti hypertensiva

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Minitran 5
Generic name:	nitroglycerin patch
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Date:	14-05-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	27-08-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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

EudraCT

CCMO

ID

EUCTR2008-008243-20-NL

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