Surgery and exercise versus exercise only for chronic patellofemoral pain syndrome: a randomised controlled trial.

Published: 13-12-2022
Last updated: 19-10-2024

Zie het onderzoeksprotocol 2: "Objectives".

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

Summary

ID

NL-OMON51505

Source
ToetsingOnline

Brief title
REVITALISE

Condition

- Tendon, ligament and cartilage disorders

Synonym
Patellofemoral Pain Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: CWZ Wetenschapsfonds

Intervention

Keyword: Patello Femoral Pain Syndorme, Tibial Tubercle Transfer

Outcome measures

Primary outcome

Zie het onderzoeksprotocol 7.1.1: "Main study parameter/endpoint"

Secondary outcome

Zie het onderzoeksprotocol 7.1.2: "Secondary study parameters/endpoints "

Study description

Background summary

Zie het onderzoeksprotocol 1:"Introduction and rationale".

Study objective

Zie het onderzoeksprotocol 2: "Objectives".

Study design

Zie het onderzoeksprotocol 3: "Study protocol"

Intervention

Zie het onderzoeksprotocol 5.1: "Investigational product/treatment"

Study burden and risks

Zie het onderzoeksprotocol 10.4: "Benefits and risks assessment, group relatedness "
The risk score of the study is classified low (*verwaarloosbaar risico*), according to the *Nederlandse Federatie van Universitair Medische Centra: *Richtlijn Mensgebonden Onderzoek (versie 2020)*.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Zie 4.2: "Inclusion criteria" in het onderzoeksprotocol.

Exclusion criteria

Zie 4.3: "Exclusion criteria" in het onderzoeksprotocol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2023
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	13-12-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-10-2023
Application type:	Amendment
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
CCMO	NL80956.091.22