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Blood flow of the knee cap in patients with knee pain

Submission date
10/12/2021

Recruitment status
No longer recruiting

Registration date
15/12/2021

Overall study status
Completed

Last Edited
29/11/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Patellofemoral pain (pain at the front of your knee, around your kneecap) is a frequent and often long-standing painful condition of the knee. Although the available scientific evidence suggests that exercise therapy is an effective treatment, there are still a lot of patients who continue to suffer from knee pain. This study elaborates on a theory of disturbed bone blood flow in the bone of the knee cap. Reduced oxygen saturation of that specific tissue potentially explains the pain while prolonged sitting and descending stairs, but this has never been studied before. Therefore the aim of the study is to observe bone blood perfusion while the participant is seated (protocol 1) and simulates descending stairs (protocol 2). The oxygen saturation will be measured with a spectroscope, which is a non-invasive device and will be placed on the skin of the knee cap.

Who can participate?
Patients with patellofemoral pain and healthy persons can participate. Patellofemoral pain is defined as pain around or behind the knee cap and usually gets worse while descending stairs or during activities like running, jumping, and hopping. Before participating in this study the principal investigator will assess the presence of patellofemoral pain and exclude other conditions of the knee that could explain symptoms. Healthy persons are required to be completely pain-free and without other specific conditions like surgery in the past. Fulfillment of these requirements for healthy persons will also be assessed by the principal investigator prior to participation.

What does the study involve?
Persons who meet the criteria described above will be asked to stay seated for 15 minutes. Thereafter the spectroscope measurements will be started and the patient bends the knee to 90 degrees and will be asked to keep in that position for 30 minutes while the measurement of bone blood perfusion will take place (protocol 1). Thereafter, the participant will be asked to stand up and simulate descending stairs (protocol 2) while again the spectroscope measurements will be performed.

What are the possible benefits and risks of participating?
By participating in this study one can contribute to developing new insights into the bone blood

perfusion and maybe change the way of thinking of best treatment strategies for this frequent and often long-standing painful condition. The Medical Ethics Committee concluded that the risks for participants are low to absent. This is due to the non-invasive character of the bone blood perfusion measurements.

Where is the study run from?
The study runs from the orthopedic surgery department of the Amsterdam Medical Centers in the Netherlands.

When is the study starting and how long is it expected to run for?
February 2021 to December 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Martin Ophey, m.j.ophey@amsterdamumc.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL77408.018.21

Study information

Scientific Title
Bone blood perfusion of the patella measured with non-invasive Near Infrared Spectroscopy in patients with patellofemoral pain

Acronym
NIRSpatella

Study objectives
In patients with patellofemoral pain bone blood perfusion of the patella bone is reduced when compared to healthy controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/11/2021, Medical Ethics Committee of the Amsterdam Medical Center (AMC, Meibergdreef 9, 1105AZ, Amsterdam, the Netherlands; +31(0)205669111; indienenmetc@amsterdamumc.nl), ref: 2021_088#B2021652

Study design
Single-center single-blinded observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Patellofemoral pain in young adults

Interventions
Bone blood perfusion will be measured with non-invasive Near InfraRed Spectroscopy (NIRS). The measurements will take place in two different postures, which usually provoke symptoms of knee pain in patients with patellfemoral pain. The first posture is prolonged sitting with the knee bend for 30 minutes and the second posture mimics descending stairs on a decline step-down exercise.

Intervention Type
Other

Primary outcome measure
Bone blood perfusion expressed as concentrations of oxygenated hemoglobin (O2Hb) and deoxygenated hemoglobin (HHb) measured using NIRS during the two conditions.

Secondary outcome measures
Measured at a single time point (baseline) unless otherwise stated:
1. Anterior Knee Pain Scale – Dutch Version (AKPS-DV), 13 item questionnaire
2. Tegner Score, 10 item level of physical activity
3. Blood pressure (mmHg), sphygmomanometer
4. Prepatellar skinfold thickness measured with Harpenden skinfold caliper
5. Patella width measured with caliper
6. Decline step-down test (DSDT) measuring pain-free flexion angle
7. Lower limb range of motion (LLROM) measuring soft tissue flexibility of the kinetic chain
8. Visual Analogue Scale (VAS) measuring pain intensity while performing protocol 1 and 2

Overall study start date
01/02/2021

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Age 18-40 years
2. Diagnosis of patellofemoral pain for more than 3 months
3. No other specific knee conditions (ACL, meniscus, OA, jumpers knee)
4. Non-traumatic onset of PFP

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
90

Total final enrolment
60

Key exclusion criteria
1. PFP due to trauma or post-surgery
2. Other specific knee conditions (ACL, meniscus, OA, jumpers knee)

Date of first enrolment
01/02/2022

Date of final enrolment
10/05/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
YsveldFysio
Nieuwstraat 9
Nijmegen
Netherlands
6511PT

Sponsor information

Organisation
Amsterdam University Medical Centers

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Sponsor type
Hospital/treatment centre

Website
https://www.amc.nl/web/specialismen/orthopedie.htm

ROR

https://ror.org/05grdyy37

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication of the protocol and the results of the study in an international well-known peer-reviewd journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/11/2023	29/11/2023	Yes	No