Ultrasound tissue characterisation for the biceps femoris long head proximal tendon: A feasibility study

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON55782

Source
ToetsingOnline

Brief title
Tendinopathy & hamstring UTC echo types: A feasibility study

Condition

- Other condition
- Muscle disorders

Synonym
Hamstring strain injuries; Hamstring tendinopathy

Health condition

Sportblessures

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hamstrings, Reliability, Tendon injury, Ultrasound

Outcome measures

Primary outcome

Ultrasound tissue characterisation echo types

Secondary outcome

standard error of measurement and intraclass correlation coefficient and

dynamic coherence (measure of the change in three-dimensional pennation angle).

Study description

Background summary

Ultrasound tissue characterisation (UTC) is a relatively new method that can be used to determine the structure of tendinous tissue. Previous studies have shown differences in Achilles and patella tendon structure between individuals with and without tendinopathy using UTC. No study has investigated whether UTC can detect differences in tendon structure between individuals with proximal hamstring tendinopathy (PHT) and individuals without PHT. Further, the intra-observer reliability of ultrasound tissue characterisation on the conjoint tendon and intramuscular tendon of the biceps femoris longhead is unknown. Finally, it is also unknown whether the three-dimensional changes in fascicle pennation structure during a passive condition and static muscle contraction can be visualised with this method and whether these changes differ between individuals with and without PHT.

Study objective

The primary aim of this study is to investigate the feasibility of using UTC to detect differences in proximal hamstring tendon structure between individuals with and without clinically diagnosed PHT. A secondary aim is to: 1) investigate the within-session intra-observer reliability of ultrasound tissue

characterization. Further secondary aims are to compare differences in echo types between the dominant and non-dominant leg and between the conjoint and intramuscular tendon of the biceps femoris within legs and investigate differences in 3D pennation structure as quantified with the *dynamic coherence* algorithm between passive and active conditions and between individuals with and without proximal hamstring tendinopathy during passive and active conditions.

Study design

Cross-sectional study

Study burden and risks

One experimental session of approximately 2 hours. The procedures are non-invasive and unlikely to lead to injuries or any other discomfort. The research will not directly benefit the participants, although all participants get information on the integrity of their tendon, which may be of special interest for patients with PHT to determine effective treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

To be eligible to participate in this study as a participant without PHT, the participant must meet all of the following criteria:
- Between 18-65 years old;
- Participating in sports that involve running, cycling or strength training for at least three two times per week.

To be eligible to participate in this study as a participant with PHT, the participant must meet all of the following criteria:

- Between 18-65 years old;
- Background in, or currently active in a sport that involves running, cycling or strength training for at least two times per week;
- Clinically diagnosed PHT.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation:- Severe visual or hearing impairment since this makes explanation of the correct position for imaging more difficult;
- BMI outside 18-25, since excessive adipose tissue around the hip region will make it difficult to get clear images of the hamstrings tendon tissue;
- Known cardiovascular or other diseases;
- In accordance with a previous study13, hypoechoic areas on the tomographic planes in the 3-D volume of the UTC measurements did not lead to exclusion.For control participants, the following additional exclusion criteria apply:-
History of a previous injury to the upper leg within the previous 5 years;
- Pain, ache or soreness in the upper leg within the previous year
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Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-04-2022
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-04-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 24776

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64767.068.18

Study results

Date completed: 02-12-2024

Actual enrolment: 4

Summary results
Trial ended prematurely