noRmativE ValuEs for Achilles tendons on uLtrasound examination

Gepubliceerd: 26-10-2020 Laatst bijgewerkt: 18-08-2022

We expect reference values for tendon structure and geometry and calf muscle strength endurance to differ between age groups and between subgroups with different levels of physical activity.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24725

Bron
Nationaal Trial Register

Verkorte titel
REVEAL

Aandoening

None

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary aim of this research project is to obtain reference values of the Achilles tendon structure (echo types I, II, III and IV) using the UTC procedure in adults without (previous)

Achilles tendinopathy.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Achilles tendon overuse injuries (tendinopathies) are frequent in middle-aged, active people. The incidence rates of Achilles tendinopathy have risen in the past decade as a result of an increasing amount of people performing (sports) activities. Achilles tendinopathy is ultrasonographically characterised by a decreased structure of the tendon fibres. The amount of structural disorganisation can be depicted with the novel Ultrasound Tissue Characterisation (UTC) technique. However, reference values for tendon geometry and structure are currently lacking. It is important to collect this information to be able to define a normal Achilles tendon geometry and structure in the general population.

Another outcome measure that is frequently used in clinical practice is the single leg heel rise endurance test (HRET) to assess the strength and endurance of the plantar flexors. Although the contralateral limb is often used as the reference for comparison of clinical HRET scores, this approach does not always reflect optimal function in the presence of bilateral deficits, previous injuries or specific populations (e.g. athletes). For these reasons, it is important to have normative HRET values

Only with this information, we will be able to define when a tendon geometry, structure and endurance strength should be considered abnormal in patients with pain in the region of the posterior ankle.

Objective: The primary aim of this research project is to obtain reference values of the geometry and structure of the Achilles tendon using the UTC procedure in the general population without symptoms of (previous) Achilles tendinopathy. A secondary aim is to concurrently obtain reference values for calf muscle endurance strength. With this information we will also be able to explore the association between UTC characteristics and functional capacity.

Study design: A cross-sectional study. The study is designed in the Erasmus MC University Medical Centre. This project is a collaboration with international institutions from Leicester (Dr. Seth O'Neil, department of physiotherapy, University of Leicester, United Kingdom), Glasgow (Dr. Neal Millar, department of Orthopaedic Surgery, University of Glasgow, United Kingdom) and Waikato (Dr. Kim Hébert-Losier, department of physiotherapy, University of Waikato, New Zealand). Data will be collected using the same procedures to be able to create a large dataset from a heterogeneous sample. The researchers from Leicester and Glasgow will send their anonymised UTC data to Erasmus MC University Medical Centre for analysis. All researchers (Leicester, Glasgow and Waikato) will send their anonymised HRET data to Erasmus MC University Medical Centre for analysis.

The sample size calculation is based on clinical experience, rather than evidence from

scientific studies. This approach is due to the fact that there are currently no large scale studies to define normative values of Achilles tendon geometry and structure. It is therefore impossible to exactly perform a sample size calculation. With inclusion of 200 participants per research centre for UTC data (600 participants in total), we expect to have a representative sample of the general population. By making this subdivision we aim to include participants with equal distribution of sex, age and activity level. The activity level will be defined the Sports Activity Rating Scale (SARS). A SARS of 60 or more points indicates a high activity level and a score of less than 60 points indicates a low activity level. This subdivision will further increase the likelihood that we will include a representative sample of the general population. In Waikato, only HRET data will be collected. The total number of participants with HRET data will therefore be 800.

Study population: Individuals aged 18 and above without current symptoms of Achilles tendinopathy and no history of localized Achilles tendon pain or stiffness.

Intervention (if applicable): Not applicable.

Main study parameters/endpoints: The main study parameter is the quantified structure (Echo types I, II, III and IV) of the Achilles tendon measured with the UTC Imaging machine Version 2020 (UTC Imaging, Stein, The Netherlands). Secondary outcomes measures are tendon geometry (maximum anterior-posterior distance, maximum medio-lateral width, maximum cross-sectional area and tendon volume) in the insertional (from Achilles tendon insertion to the proximal part of the calcaneus; classically 0-2 cm of the Achilles tendon insertion) and midportion (the free part of the Achilles tendon above the calcaneus; classically 2-7 cm proximal of the Achilles tendon insertion) area. A secondary study parameter is the calf muscle strength-endurance, measured with the standardized single leg heel rise endurance test (HRET) using the Calf raise Application.

Statistical analysis:
Primary study parameter(s)
The UTC echo-type parameters are continuous data. The analysis will be stratified into right leg and left leg. The normality of distribution of the data will be tested with the Shapiro-Wilks test. In case of normal distribution of data measures of central tendency (mean) and corresponding reference ranges (standard deviation) will be calculated. The 95th percentile reference range (+/- 2SD) will be determined. In case of non-normal distribution, measures of central tendency (median) and corresponding reference ranges (interquartile range) will be calculated accordingly.
As initial step, data will be inspected using scatterplots to identify outliers, relationships between variables, and interaction effects. Subsequently, a multiple regression model will be performed using the covariates and the interaction effects found that significantly influence the primary outcome measure. Statistics will be performed using SPSS. The significance level will be set at $p < 0.05$ ($\alpha = 0.05$) for all tests.

Secondary study parameter(s)
The Achilles tendon geometry (maximum anterior-posterior distance, maximum medio-lateral width, maximum cross-sectional area and tendon volume) and calf muscle strength endurance (number of repetitions, vertical height loss (%), total vertical displacement (cm),

power (watt), and work (joule)) will be handled as secondary endpoints. The analysis will be stratified into right leg and left leg. In case of normal distribution of data measures of central tendency (mean) and corresponding reference ranges (standard deviation) will be calculated. The 95th percentile reference range (+/- 2SD) will be determined. In case of non-normal distribution, measures of central tendency (median) and corresponding reference ranges (interquartile range) will be calculated accordingly.
As initial step, data will be inspected using scatterplots to identify outliers, relationships between variables, and interaction effects. Subsequently, a multiple regression model will be performed using the predefined covariates and the interaction effects found that significantly influence the secondary outcome measures. Linear regression models will also be used to identify correlations between tendon structure and calf muscle strength endurance parameters.

Other study parameters
Anthropometric Characteristics (age, gender, mass, Body Mass Index; BMI and leg dominance) presence of co-morbidities, medication use that can influence tendon health, smoking status, alcohol use, and current and past physical activity (6-point Likert scale and SARS score), will be handled as additional parameters collected in this study.
Linear regression models will be used to identify correlations between both the primary and secondary endpoint and the following variables: age, gender, BMI, leg dominance, co-morbidities, medications, smoking, alcohol use and current and physical activity measures (6-point Likert scale and SARS score).
We will perform a subgroup analysis of patients without fusiform swelling using the arc test and/or localized pain on Achilles tendon palpation. As these signs could still be present in asymptomatic people, it is debatable whether these features are representative of a normal tendon. Therefore we plan to perform a sensitivity analysis.
We aim to develop unsupervised machine learning algorithms. The algorithm will be used to uncover patterns and features within tendon images without any assumption about how an optimal tendon may look.

Doel van het onderzoek

We expect reference values for tendon structure and geometry and calf muscle strength endurance to differ between age groups and between subgroups with different levels of physical activity.

Onderzoeksopzet

Both primary and secondary outcome measures will be measured on one time point. Below the detailed descriptions how and in what order the outcome measures will be obtained.
The study will be promoted through existing social media platforms and the participating organisations as describes above (e.g. the local authorities of the city where the research locations are established, in healthcare centres or blood banks). All potentially eligible participants will be informed about the study. When potentially eligible participants are interested, they will complete a short questionnaire to assess eligibility. If the inclusion criteria are met, the participants will be asked to sign the written informed consent form. A more extensive questionnaire will be completed with collection of demographic data, health,

sports activity. Current symptoms will be evaluated using the adapted VISA-A questionnaire (Q1-Q5). Full score on this questionnaire is required. Thereafter a short physical exam will be performed (assessing localized pain on Achilles tendon palpation and localized tendon thickening using the Arc sign. Subsequently, the UTC procedure will be carried out on both Achilles tendons. Finally participants will perform a HRET. During this test, participants will adopt a single leg stance, barefoot, with full knee extension and trunk erect on a 10° incline box. Only fingertip support (index and middle finger) at shoulder height on the wall in front of them is allowed. Participants will be instructed to raise the heel as high a possible on each repetition, return the heel to the board and to perform as many heel rises as possible. The heel rise needs to propel the body vertically with little anterior movement occurring. During testing, participants will be verbally instructed to maintain the test parameters regulating heel excursion, cadence, balance support and knee angle. A digital metronome at a rate of 60 heel rises per minute is used to guide the pace of the heel rises, going up on one beat and down in one beat. Prior to testing each subject will perform 10 bilateral standing heel rises as a warming up to the pace of the metronome. The HRET will be performed once on each leg. Each participant is tested on the right and left leg in a quasi-randomised order. This order is decided prior to the test session and based on moment of inclusion. Each participant will first perform the HRET with the opposite leg compared to the previous participant. After the first single leg HRET participants will get 2 minutes rest, whereafter the test will be performed with the opposite limb.Testing will be terminated when participants can no longer lift the heel from the incline box, when they can no longer maintain the knee angle or trunk position, or use the wall to assist performance. After the HRET, participants will be asked whether they experienced pain in their Achilles tendon and if so, how much pain on a Visual Analogue Scale (VAS). Using the specially designed Calf Raise Application and a round sticker placed on the foot, each heel-rise test will be recorded on video. The number of heel rises for each leg will be used as outcome score. By tracking a pre-set point on the Achilles tendon, the Calf Raise application will measure number of repetitions, vertical height loss (%), total displacement (cm), power (watt) and work (joule).

The UTC device is portable, which enables us to perform the procedure on multiple locations. At all times the location will guarantee the privacy of the participants. The UTC procedure is a validated technique to quantify the structure of the Achilles tendon by categorizing tendons in echo type I to IV. The four echo types are based on the stability of intensity and distribution in contiguous transverse images. The UTC measurements will be performed by an experienced examiner

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Erasmus MC, Rotterdam
Tjerk Sleeswijk Visser

-

Wetenschappelijk

Erasmus MC, Rotterdam
Tjerk Sleeswijk Visser

-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ≥ 18
2. No current localized Achilles tendon pain or stiffness
3. No localized visible fusiform thickening of the Achilles tendon
4. No medical history of pain or stiffness of the Achilles tendon region
5. Full score on the adapted VISA-A questionnaire (question 1 – question 5)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Achilles tendon or ankle surgery in the past
2. Known systemic inflammatory disorders or internal diseases that can cause Achilles tendon pain (e.g. Spondylarthropathy, Psoriatic Arthritis or Familial Hypercholesterolaemia)
3. Recent (past 12 months) lower-limb injury requiring immobilisation
4. No written consent provided

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-10-2020
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	26-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9010

Register	ID
Ander register	METC Erasmus MC : MEC-2020-0585

Resultaten