The Recovery after Achilles Tendon Rupture: an Exploratory Cohort Study

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Primary Objective: To explore factors contributing to optimal patient ATR recovery (subjective, functional, imaging)Secondary Objectives: 1. To gain insight into the course of the recovery phase of the ATR via multiple parameters2. To gain insight...

Ethical review	Approved WMO
Status	Completed
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45706

Source
ToetsingOnline

Brief title
The Recovery after Achilles Tendon Rupture

Condition

- Tendon, ligament and cartilage disorders

Synonym
Achilles tendon rupture

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Achilles tendon, Rupture, Ultrasound tissue Characterisation

Outcome measures

Primary outcome

At 3 months the baseline patient and injury information will be collected by means of a baseline questionnaire and the patient medical file. Patient data consists of biographical information, anthropometrics, lifestyle factors, co-morbidities. Injury data concerns etiology and extent and management applied.

At 3, 6 and 12 months months post injury the following data will be collected:

-Management complication information from patient status

-Subjective: Dutch versions of the Achilles Tendon Total Rupture Score (ATRS-NL),) Euroqol-5D (EQ-5D), OSTRC Overuse Injury Questionnaire, Injury Psychological Readiness Return to Sport Scale (I-PPRS), Tampa Scale of Kinisiophobia (TSK), Expectations, Motivations and Satisfaction Questionnaire, Reasons Failed Return to Sport (at 6 en 12 maanden)

-Functional/Clinical: heel-rise test (strength), range of motion (ROM), tendon length, and single leg hop for distance (at 12 months)

-Imaging: Ultrasound tissue characterisation (UTC)

-Economical: Productivity Cost Questionnaire (iPCQ) and Medical Consumption

Questionnaire (iMCQ)

Secondary outcome

-Recovery complications (e.g re-rupture, infection) (from medical status) and

return to work/sport (from OSTRC Overuse Injury Questionnaire).

Study description

Background summary

The Achilles tendon is the strongest and thickest tendon in the human body. Despite this, the Achilles tendon is the most frequently ruptured tendon. The etiology of an Achilles tendon rupture (ATR) is usually traumatic but it can be due to other factors (medications, tendinopathy, hyperthermia, degenerative change). The ATR has an acute presentation of severe pain. Patients report a feeling of *being kicked* in the posterior aspect of the distal part of the affected leg.

The incidence of the ATR is steadily increasing globally. Although the exact incidence in the Dutch population is unknown, Sode et al. showed that in Denmark the incidence has steadily increased from 22.1/100,000 in 1991 to 32.6/100,000 in 2002 (4). Recent research in a USA population has shown that especially in the middle aged (30-50) the ATR is rising, establishing itself as one of the most common treated injuries by orthopedic surgeons (5). This increase in incidence is also expected in the Netherlands, especially given the promotion of and strong emphasis on Healthy Ageing in the Netherlands, the ageing population and possibly also obesity. Sport participation and exercise play a major role in ATR development, and hence the expected increased activity in the scope of the *exercise is medicine* philosophy of the Healthy Ageing initiative, may establish an increase in incidence.

Despite the confirmed increasing incidence, a clear management consensus for the ATR is lacking. The guidelines of the American Academy of Orthopedic Surgeons (AAOS) have a limited or inconclusive recommendation for the role of imaging, the choice of treatment, and the form of rehabilitation in the clinical protocol of ATR patients. Additionally, Kolfschoten et al. stated that there is insufficient scientific evidence to construct a conclusive management protocol in the Netherlands. Currently, management decisions depend mostly on the experience of the practitioner who sees the patient first (surgeon or sports medicine physician). Surgical and conservative treatment are both

supported by literature and the recovery (rehabilitative) phase starts at 3 months post-injury, as recommended bij the AAOS. A recent Systematic Review of Randomized Controlled Trials (RCTs) by Holm et al. concluded that the difference in outcome between surgical and conservative treatment of ATRs is minimal . Because guidelines are inconclusive and RCTs show the difference in outcome based on primary treatment (surgery or conservative) is not significant.

Furthermore, no research has taken cost-effectiveness into account when analyzing management options for ATRs. To contribute to an ATR guideline it is therefore essential to enhance knowledge concerning the optimal management for the patient but also the public.
Up to now, the used imaging modalities such as ultrasound have no additional role in ATR recovery monitoring. We plan to examine the potential for an applicable ATR monitoring device, especially given the increasing emphasis placed on outcome parameters after the rehabilitative phase. Van Schie et al. concluded that Ultrasound Tissue Characterisation (UTC) might be useful in Achilles tendon disorder monitoring. This device quantifies and characterizes tendon structure itself, and standardizes operator-dependent variables (unlike conventional ultrasound or MRI). However, van Schie et al. focused solely on tendinopathy, its value within ATR monitoring remains inconclusive.

Finally, with respect to ATR there is no research concerning the decisions to return to sport, and a recent systematic review determined only 80% actually return to sport (10). It is not known if psychological variables are connected with multiple outcomes (subjective, functional/clinical) in patients with ATR. The association of such psychological factors, outcome and return to sport in patients with ATR has to be examined to optimize the rehabilitation process.

This project strives to expand on prior research and create more clarity on proper ATR management and recovery by examining multiple factors. Recovery will be assessed through multiple outcomes (subjective, functional/clinical, and imaging). This study strives to explore optimal management decisions as well as (barriers to) return to sport for specific patient groups. The cost-effectiveness of the protocol administered to each patient will additionally be gathered. The UTC device, which is already being applied in a clinical research setting in the UMCG, will be used as a measurement of tendon tissue integrity and quality.

Study objective

Primary Objective:
To explore factors contributing to optimal patient ATR recovery (subjective, functional, imaging)

Secondary Objectives:
1. To gain insight into the course of the recovery phase of the ATR via multiple parameters

2. To gain insight into the cost-effectiveness of ATR management
3. To gain insight into (barriers to) return to sport

Study design

Multicenter Exploratory Cohort Research

Study burden and risks

Each patient will be subject to 3 visits in 12 months at their treating hospital. Every visit will take 40 minutes. The following measurements will be made:

- We will retrieve injury en management data from the patient's medical file
- We will administer a initial "baseline" questionnaire about patient/injury data - at 3 months
- We will administer questioannires about the patient recovery - at every visit
- We will perform functional tests - at every visit
- We will administer a UTC analysis - at every visit

Contacts

Public
Selecteer

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NL
Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Be older than 18 years of age at the time of inclusion
-Have been clinically diagnosed with an Achilles tendon rupture and have been treated less than 3 months ago at the UMCG, Martini Hospital or MCL
-Give written informed consent

Exclusion criteria

-Unable to understand Dutch
-Inability to perform and or understand the tests and/or questionnaires

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-07-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	17-05-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-09-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-10-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 29205
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59714.042.17
OMON	NL-OMON29205