The Recovery after Achilles Tendon Rupture

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29205

Source
NTR

Brief title
The Recovery after ATR

Health condition

(Complete) Achilles Tendon Rupture

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: University Medical Center Groningen (UMCG)

Intervention

Outcome measures

Primary outcome

At 3 months post-injury the following (predictive) data will be collected by means of a questionnaire and digital patient (medical) status: patient (biographical information, anthropometrics, lifestyle factors, co-morbidities), injury (ATR etiology and extent) and management (operative or conservative) data.

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

Subjective: Achilles Tendon Total Rupture Score (ATRS-NL), the Euroqol-5D (EQ-5D), Oslo Sports Trauma Research Center (OSTRC) Overuse Injury Questionnaire, Injury Psychological Readiness Return to Sport Scale (I-PRRS) scale, Tampa Scale of Kinesiophobia (TSK), a study-specific questionnaire on Expectations, Motivation & Satisfaction questionnaire and reasons for failed RTS questionnaire (6 and 12 months)

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

Imaging: Ultrasound Tissue Characterisation (UTC)

Economic: Productivity Cost Questionnaire (iPCQ) and Medical Consumption Questionnaire (iMCQ)

Secondary outcome

Recovery complications

Study description

Background summary

Rationale: Despite the acute nature and increasing incidence of the Achilles tendon rupture (ATR) there are currently no management guidelines available on treatment, rehabilitation, return to work/sports and functional recovery in the Netherlands. Moreover, the internationally published diagnostic, treatment, and rehabilitation guidelines are determined inconclusive and they lack consensus. Little data exists on patient subjective and functional recovery or predictors of optimal recovery of ATR. Additionally, the role of imaging in the monitoring of recovery is inconclusive. Only a few studies have combined multiple outcomes in assessing ATR recovery (subjective, functional/clinical, and imaging) or examined alternative imaging devices for ATR monitoring. No studies on the cost-effectiveness or barriers to return to sport (RTS) of ATR exist.

Objectives:

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 after ATR via multiple parameters

2. To gain insight into the cost-effectiveness of ATR management

3. To gain insight into (barriers to) RTS

Study design: Multicenter exploratory cohort study

Study population: Adult patients having suffered an ATR and treated within 3 months

Follow-up: 3, 6, and 12 months post-injury

Primary Endpoints

-The relationship between subjective, functional/clinical and imaging outcomes at 3, 6, and 12 months post-ATR and patient/injury/management data.

Secondary Endpoints:

-Changes in recovery outcomes, recovery complications (e.g. re-rupture, infection) and time out of work/sport (from questionnaires).

-Incremental Cost Effectiveness Ratio (ICER) calculation = (Costs of treatment - Costs of

alternative)/ (Effects of treatment– Effects of alternative) from iPCQ, iMCQ and EQ-5D results at 3, 6, and 12 months.

-The relationship between psychosocial factors and RTS

Study objective

Exploratory study on the recovery after Achilles Tendon Rupture (ATR)

Study design

Follow-up at 3, 6, and 12 months post-injury

Intervention

Not applicable

Contacts

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Eligibility criteria

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 University Medical Center Groningen (UMCG), Martini Hospital or Medisch Centrum Leeuwarden (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
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2017
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-06-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45706
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6309
NTR-old	NTR6484
CCMO	NL59714.042.17
OMON	NL-OMON45706

Study results