Acute Achilles tendon rupture: Minimally invasive surgery versus non operative treatment, with immediate full weight bearing. Design of a randomized controlled trial.

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Abstract

**Background:** We present the design of an open randomized multi-centre study on surgical versus conservative treatment of acute Achilles tendon ruptures. The study is designed to evaluate the effectiveness of conservative treatment in reducing complications when treating acute Achilles tendon rupture.

**Methods/Design:** At least 72 patients with acute Achilles tendon rupture will be randomized to minimally invasive surgical repair followed by functional rehabilitation using tape bandage or conservative treatment followed by functional rehabilitation with use of a functional bracing system. Both treatment arms use a 7 weeks post-rupture rehabilitation protocol. Four hospitals in the Netherlands will participate. Primary end-point will be reduction in complications other than re-rupture, notably infection, disturbed wound healing and disturbed sensibility in the sural nerve area, adhesions and thrombosis. Secondary end-point will be re-rupturing, time off work, sporting activity post rupture and patient satisfaction. Patient follow-up will be 12 month.

**Trial registration:** ISRCTN50141196
Background

Controversy continues with regard to the optimal treatment for acute subcutaneous Achilles tendon (AT) ruptures. Treatment can be classified into operative (open or minimally invasive) and non-operative. Post operative splintage can be divided into cast immobilisation and functional bracing.

Traditionally operative repair of a ruptured Achilles tendon has been the first choice of treatment due to low re-rupture rates and the possibility for functional post-operative splintage. [1-4]. But, 34% of patients treated with open repair suffer from complications other than re-rupture, especially wound infection and adhesions [1-5]. In general, the outcome of treatment of a re-rupture is poor, but results following treatment of a deep infection are devastating [6]. Therefore an effort should be made to prevent infectious complications. A less invasive method could reduce infectious and other complications. It diminishes the damage to the peritendineum and decreases damage to the delicate blood supply of AT.

Importantly, minimally invasive surgery allows functional rehabilitation after operation [7]. Patients treated with functional bracing after operation rather than cast immobilisation tend to have a shorter in-patient stay, less time off work and a quicker return to sporting activities. There is also a trend for a lower complication rate including re-ruptures [1-5].

Many cohort studies on different types of minimally invasive repair of ruptured AT’s have been published [7-14]. To date only 2 randomized trials [4,15] have been reported. They show comparable re-rupture rates with less other complications compared to open repair. Still, data are limited. The sural nerve however, might be increasingly at risk with minimally invasive surgery and infections and adhesions may occur. Therefore there is an ongoing pursuit for less invasive treatment options, mainly conservative treatment.

The main advantage of conservative, i.e. non-operative treatment is elimination of wound complications and intra-operative sural nerve damage. Complications other than re-rupture are
reduced to 3% [5]. But, conservative treatment with cast immobilisation has shown to increase the re-rupture rate is some series [1,5]. A disadvantage of conservative treatment by cast immobilisation however is delayed recovery with calf muscle weakness due to long immobilisation of the ankle joint. In contrast, conservative treatment by functional bracing does allow immediate weight bearing, preventing calf muscle weakness and enabling fast recovery. Data from three studies on conservative treatment of AT rupture with functional bracing show no increase in re-rupture rates [16-18], but only one of them is a randomized trial [17].

Although conservative treatment with functional bracing seems to be able to reduce complications without increasing rerupture rate and has the advantage of being a functional means of splintage more prospective randomized data are needed to confirm this.

The primary goal of our study is to see if conservative treatment with functional bracing reduces the risk of complications other than re-rupture compared to operative treatment. These complications include infection, disturbed wound healing and disturbed sensibility in the sural nerve area, adhesions and thrombosis. If conservative treatment of acute Achilles tendon ruptures using functional bracing is effective in terms of reducing the complication rate, the rerupture rate should not increase.

Methods/Design

Design of study

Context: The efficacy of minimally-invasive surgery versus functional non-surgical treatment of acute subcutaneous Achilles tendon ruptures will be studied in a randomized trial. Four hospitals in the Netherlands will participate in the study, one of them being a university medical centre. The Medical Research Ethics Committee of all the participating hospitals approved the study protocol.
Patient selection and informed consent: All patients who report to the emergency department of one of the participating hospitals with an acute Achilles tendon rupture will be considered for entering the study protocol. Inclusion and exclusion criteria are listed in table 1 and will be checked by an emergency room doctor, surgical resident or surgeon. All eligible patients are asked to provide written informed consent.

Randomisation and blinding: Randomisation is concealed by a specially designed internet site. Randomisation is in blocks (4 blocks) and stratified by centre. The treatment nature is open labelled for patients, physicians and physiotherapists. During follow-up visits physical examination reveals the allocated treatment to patient and assessor.

Interventions: Operative therapy consists of a minimally-invasive technique [7]. A small longitudinal incision is made over the posterior aspect of the affected leg just proximal to the rupture site. The incision is slightly medially placed. The subcutaneous fat is divided and the peritendineum opened. Then a Bunell type suture is placed though the proximal end of the Achilles tendon (PDS 1.0). With a hollow mandarin the suture is tunnelled to the lateral aspect of the calcaneal bone. A hole is drilled through the calcaneal bone 1 cm distal to the tendon insertion. The PDS in guided though the hole. Now the mandarin is used to guide the suture back to the proximal site of the tendon. After the foot is placed in plantar flexion the suture is tied. After wound closure a cast is applied with the foot still in plantar flexion. After one week a tape bandage is applied for a total period of 6 weeks. In the first two weeks the tape bandage is supported by a 2 cm heel raise. The following 2 weeks the heel raise is reduced to 1 cm. The last two weeks the heel raise is removed (tape bandage will be renewed every time the heel raise is changed). Full weight bearing is allowed during the 6 weeks of tape bandage, not allowing sporting activities.

Conservative therapy consists of a cast in plantar flexion for one week. After one week a functional bracing system [19,20] is applied for 6 weeks. In the first two weeks the brace is
rigid in 30 degrees plantar flexion. The following 2 weeks in is in rigid 15 degrees plantar flexion. The last two weeks the brace is dynamic from neutral position to 30 degrees plantar flexion. Full weight bearing is allowed during the 6 weeks of bracing, not allowing sporting activities.

**Design of collection of data**

Primary endpoint: complications, i.e. infection, disturbed wound healing, disturbed sensibility in the sural nerve area, adhesions, thrombosis and all other complications per treatment group. Secondary endpoint: re-rupturing, time off work, sporting activity post rupture and patient satisfaction. Time off work will be registered by a patient diary. Patient satisfaction will be measured by VAS-sores at 7 weeks, 3 and 12 month. Subjective patient outcome will also be evaluated by a clinical scoring form based on the Leppilahti scoring method [21].

Follow-up: Follow-up visits for assessment of primary and secondary endpoints will be scheduled every week during the first 7 weeks. Thereafter, follow-up visits will be planned at 3, 6 and 12 month. Any other consultation for complaints concerning the Achilles tendon area will be documented.

**Design of analysis**

Data analysis: The study groups will be compared for their baseline characteristics. The number of complications will be calculated for the primary endpoint. Distribution measures will be calculated for the secondary endpoints at the different moments of follow-up. Differences between groups for the number of complications and distribution of other endpoints will be calculated for each outcome measure with a 95% confidence interval. The study groups will be compared with the chi-square test for categorical outcome variables and the independent sample Student t test for continuous outcome variables.
Sample size is calculated on the basis of complication rate, notably infection, disturbed wound healing and disturbed sensibility in the sural nerve area, adhesions and thrombosis. In open repair these complications occur in 34% of the patients [5]. Conservative treatment with this new type of functional bracing is expected to reduce this complication rate by 30%. We used a 2-sided $\alpha$ of 0.05, a statistical power of (1-\(\beta\)) of 0.80. This leads to a calculated sample size of 32 patients in each treatment group. Including attrition rate of 10% we need at least 72 patients to enter the protocol.

Comments

This study is primarily designed to evaluate the effectiveness of conservative treatment of acute AT ruptures, using a functional bracing system, in reducing complications other than re-rupture. A comparison is made between this functional bracing system and a minimally-invasive operative repair of acute AT ruptures. Both treatment options used in this comparison allow immediate full weight bearing so none of the patients is denied the purported advantage of a functional after treatment [2,5,22-25]. There have been randomized clinical trials on treatment of acute Achilles tendon rupture but the methodological rigour is often low. There is a need for more rigorous designed studies on AT rupture treatment as this subject is still very much under debate. By publishing our protocol we wish to show our care for a profound design and methodological quality of our protocol. Moreover, when the design of a study is published it will help to achieve transparency about why and how studies are undertaken. The publication of a study design may help to reduce the problem of publication bias, i.e. selective publication of positive associations and disregarding negative and weak associations, prevent unnecessary duplication of research efforts and duplicate publication [26]. To our knowledge, there has never been a design study published regarding treatment of AT ruptures. By making this
design study we wish to contribute to more profound research on AT rupture treatment and prevent publication bias for this open-labelled randomized trial.
Authors' contributions

RM main author of study design.

GK first initiated the trial and participated in designing the treatment protocol for operative and non-operative treatment.

EV first initiated the trial. Especially involved in all clinical aspects of the trial and study design.

GH contributed to methodology and statistics in study design.
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**Inclusion criteria**  |  **Exclusion criteria**  
---|---
Primary spontaneous Achilles tendon rupture. | Re-rupture / bilateral rupture / open rupture.
Treatment starts within 72 hours after rupture. | Combination with fracture of foot or ankle.
Diagnoses by physical examination: palpable gap and calf muscle squeeze test positive for tendon rupture. | Former application (injection) of local corticosteroids in tendon area.
Age 18-65 years. | Contra-indications for surgery.
Informed consent. | Physical or mental handicaps that do not allow functional treatment or otherwise interfere with the ability to follow-up on the study protocol.

**Table 1: In-and Exclusion criteria**