

# Exercise Therapy for Patellar Tendinopathy Evaluated With Advanced UTE-MRI

NCT02938143

20-01-2019

## Statistical analysis plan JUMPER-study

Participants will be analyzed by intention-to-treat. To test for the effect on the between-group difference in primary outcome (VISA-P score), we will use the Generalized Estimating Equation (GEE) model. Adjustments will be made for the following baseline variables: age, sex, BMI, duration of symptoms and activity level (Cincinnati Sports Activity Scale). The same approach will be used for the following secondary outcomes: VAS score on palpation of the proximal patellar tendon, VAS score in the patellar tendon during single leg decline squat before and after isometric exercises, VAS score during the latest sport activity, VAS score during activities of daily living, muscle force and flexibility of upper and lower leg muscles, vertical jump height and two dimensional video-based analysis of the drop vertical jump test.

Compliance to the exercise therapy and the amount of experienced pain (VAS 0-10) will also be analyzed in a secondary analysis to test for the effect of compliance on the primary outcome using the GEE-model.

This GEE-model will also be used to determine the association between the following variables and the course of symptoms resulting from patellar tendinopathy: the level of passive coping (measured with the Pain Coping Inventory) and presence of a neuropathic pain component (measured with the painDETECT questionnaire).

Fisher's exact test will be performed for the following categorized secondary outcomes: return to desired sport and subjective patient satisfaction, which we will dichotomize, for the following categories (A) return to desired sport at pre-injury level, (B) return to desired sport, but not at pre-injury level, (C) return to sport, but not to desired sport, (D) no return to sport and (A) excellent, (B) good, (C) moderate, (D) poor, respectively. For example, return to desired sport at pre-injury level (1) and other categories as (0) and excellent/good as satisfied (1) and moderate/poor as dissatisfied (0), for return to sport and subjective patient satisfaction respectively.

Missing data will not be imputed to avoid the introduction of biased estimates of treatment effect. We chose this approach because it is likely that missing data will not occur at random. This assumption is based on the facts that patients are not blinded to the allocated therapy and one exercise program is expected to cause significantly more pain than the other exercise program. Therefore, only a sensitivity analysis will be performed if missing data is more than 5%, blinded for the allocated exercise therapy.

We intend to publish results of this study in multiple papers, given the large amount of data derived from this randomized controlled trial.