The Value of a High-Volume Image-Guided Injection in Chronic Midportion Achilles Tendinopathy: a Double-blind, Randomized, Placebo-controlled Clinical Trial

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Statistical analysis plan HAT-study

The patients will be analyzed by intention-to-treat. To test for the effect of treatment on the between-group difference in primary outcome(VISA-A score), we will use the Generalized Estimation Equitions (GEE) model. Adjustments will be made for the following baseline variables: age, sex, BMI and duration of symptoms. The same approach will be used for the following secondary outcomes: modified Öhberg score (0-4+ score), VAS score during 10-hop test, flexibility m. gastrocnemius, flexibility m. soleus, power m. gastrocnemius, power m. soleus.

Fisher's exact tests will be performed for the following secondary outcomes: Return to desired sport (categorized, we will dichotomize for: no return to sport and return to sport, not to desired sport combined as no return to sport; return to sport, not at pre-injury level and return to sport at pre-injury level combined as return to sport), patient satisfaction (categorized, we will dichotomize for: good/excellent as satisfied, moderate/poor as dissatisfied), and patient acceptable symptoms scale (PASS; categorized, symptoms acceptable/not acceptable).

Missing data will not be imputed, however sensitivity analyses will be performed if missing data is more than 5%. The researcher who will perform the analyses will be blinded to the allocated treatment. No interim analyses were planned for this study. Given the large amount of data derived from this trial, we intend to present the results in multiple papers.

Update 12-8-2019: We excluded the baseline VISA-A score as adjusted variable in the GEE-model, since adjustments are already being made as the baseline VISA-A score is included in the model as time point. Therefore, our biomedical statisticians stated that it was not necessary to adjust for this variable twice.