Sponsor : **PROTEOR**

Official title:

Evaluation of a New Microprocessor-Controlled Prosthetic Knee : A Prospective, Multicentered, Randomized Cross-over Trial

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STATISTICAL ANALYSIS PLAN

The number of participants for whom the outcome measure ware measured will be analyzed. The number of participants analyzed will be described. Expected number: 18. The population will be described in terms of anthropometric data and assigned arm.

Each subject will be included in one of 2 arms:

- Start using current MPK for 4 weeks before fitting new MPK and use it for 4 weeks
  OR
- Start using MPK_NEW for 4 weeks before fitting back current MPK and use it for 4 weeks

The average PSFS score will be described for each subject and for each Microprocessor-controlled knee: current (MPK_HAB) and new (MPK_NEW). The main criteria measure will be **the difference of the averages** paired by the two conditions (MPK_NEW – MPK_HAB).

Distribution normality will be tested with Shapiro-Wilk tests; superiority tests will be run. A **t-Test, 1-sided** (student test) will be used if the dataset follows a normal distribution. Otherwise, the **Wilcoxon test** will be used. The P-value for significance is 0.05.

PSFS scores for each condition (MPK_HAB and MPK_NEW) will also be presented as means and standard deviations.

Secondary outcomes measures such as functional tests will be described for each condition as means and standard deviations. The t-test will be used for analysis if dataset follows a normal distribution. Otherwise, the Wilcoxon test will be used. For questionnaires, answers and scores will be analyzed for each condition.