

Non-invasive molecular imaging to determine the hemoglobin and collagen content in muscles before and after physical exercise and over time (MSOT_muscles)

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Statistical Analysis Plan

The present study is a pilot proof-of-concept study. Due to lack of clinical trials in this area, the comparative changes of MSOT spectra and signals within and between examiners, before and after exercise, over time and between different muscles and muscle positions are unknown. Therefore, no sample size calculation was performed.

The primary outcome measure is to assess the reproducibility of the muscular optoacoustic spectra of healthy volunteers facing different variables (examiner, time, exercise, muscle position).

MSOT signals are derived from averaged video captures (seven frames) obtained in anatomical independent muscle regions in patients. All anatomical locations are considered independent. In cases of multiple scans/recordings, a mean of all analyzed scans is calculated.

Continuous variables are given as means and standard deviations; categorical variables are provided as numbers and percentages. Data are tested for normal distribution using Shapiro-Wilk test prior to inferential analysis. MSOT signals are compared matched manner using a paired t-test when parametric and a Wilcoxon matched-pair signed rank test when non-parametric. For the comparison of three or more groups analysis of variance (ANOVA) and for nonparametric distribution Friedman Test is used. Correlations are specified with the parametric Pearson correlation coefficient (r) and the nonparametric Spearman correlation (r_s), using a 95% confidence interval. Additionally, the intraclass correlation coefficient (ICC) will be used with the grading proposed by Landis and Koch. For all analysis an error level of $p < 0.05$ is considered as statistically significant. All analyses are performed using GraphPad Prism (Version 8, GraphPad Software, La Jolla, CA, USA) and/or IBM SPSS Statistics (Version 24, IBM Corp., N.Y., USA).