Test-retest Reliability of Measuring the Area and Intensity of Secondary Hyperalgesia Induced by High Frequency Stimulation of Skin Nociceptors

Statistical Analysis Plan (SAP)
May 27th, 2019
[NCT ID not yet assigned] [Protocol ID : HFS reliability]

For this study, we will recruit 32 subjects.
This is because a random sample of 32 subjects who are each measured 6 times produces a two-sided 95% confidence interval with a width of 0,100 when the estimated intraclass correlation is 0,900.

Statistical analysis will be conducted with the SPSS software (version 25).

Statistical analysis will include intraclass correlations (ICC) for the 3 measures repeated in the same session, and to compare measures from session 1 and session 2 (single values and averages of the 3 measures). ICCs will be calculated using a two-way random-effects ANOVA model. Standard error of the mean (SEM) and the minimal detectable change (MDC) will then be calculated. Furthermore, we will assess the agreement between repeated measures with Bland Altman plots.

Finally, we will assess if the area and the intensity of hyperalgesia is modulated by our secondary outcomes (weight, electrical detection threshold, age, gender, state/trait catastrophization, stress during HFS, trait/state anxiety, pain during HFS). This will be assessed by a univariate linear regression, followed by a multivariate analysis.