Title: Effect of high vs. low dose intravenous dexamethasone on complications in the immediate postoperative phase after periacetabular osteotomy (DEX-GANZ).

NCT number: NCT03161938

Document date: 16-05-2018

Statistical Analysis Plan

Dichotomous variables are presented as numbers with percentages, and between-group comparisons are assessed with the Fisher exact test. Ordinal variables are presented as median with interquartile range. Continuous variables are assessed for normal distribution with the Shapiro-Wilk test and/or visual examination of histograms and normal QQ-plots. Normally distributed data are presented as mean ± SD and otherwise as median with interquartile range. Test for significant differences between groups is performed with an independent-samples t-test (normal distribution) or Mann-Whitney U test (non-normal distribution). Data from the questionnaire on PONV and sleep is dichotomized into categories, PONV/no PONV and sleep problems/no sleep problems and assessed as described for dichotomous variables.

Comparison of group differences of pain from the questionnaires is analysed in a two-way ANOVA model (factors being day and group), taking into account the repeated measurements on the same individual (a mixed model with compound symmetric covariance structure).

All available data are used. Missing data mainly occurred in the questionnaires and is assumed to be missing at random. Cases missing all data were ignored (listwise deletion).

Data analyses are conducted using SPSS for Windows, version 25 (IBM Corp., New York, USA) and R for Windows, package version 1.0.153 (R foundation for Statistical Computing, Vienna, Austria) (or newer versions, depending on availability). Author (KS) conducts all analyses, that will be evaluated by HNA. Statistical consultancy will be used for the mixed effects model.All available data are used, missing data is not imputed.

Data processing is done by the investigator, who will continue to be blinded until all results are analyzed, and the abstract is written and accepted by co-authors.