EFFECT OF DEXMEDETOomidINE ON POSTOPERATIVE GLUCOSE AND INSULIN SECRETION PATTERNS IN OBESE PATIENTS WITH IMPAIRED GLUCOSE TOLERANCE

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Statistic Analysis Plan (SAP):
Sample size based on the primary objective is calculated as follow: Using a standard deviation of 20.6mg•dl⁻¹ on the plasmatic glucose levels, 17 patients per group would be needed to find a difference in the glycemic values of 20 mg•dl⁻¹ between groups, with a power of 0.80 and an alpha value of 0.05. Our goal is to enroll 20 patients per group, to allow possible dropouts from the study.

The tendency analysis on the glycemic and postoperative insulin levels is carried out using mixed linear models (PROC MIXED SAS 9.2). As predictor variables we include "group" (dexmedetomidine / placebo) and "time" (repeated measurements), plus the "group and time" interaction. The effect is adjusted by the variables "glycemic baseline value" and "HbA1c value". The value of the Akaike Information Criterion (AIC) is used to define the best structure of the covariance matrix. The analysis follows the intention-to-treat principle.