

Stanford IRB Protocol #: 57772

Study Title: Fasting versus fed: Effect of oral intake prior to the glucose tolerance test in pregnancy

Principal Investigator: Dr. Yair Blumenfeld

NCT#: 04547023

Date: May 20, 2022

STATISTICAL PLAN:

To detect a difference of at least 20 percentage points in the percent screen positive between the fasting and fed groups, we calculated the study will require 88 women per group (total N=176), assuming two- sided $\alpha=0.05$, power=0.8, a two-sample Pearson's chi-squared test. Accounting for approximately 10% attrition after initial enrollment, we increased our sample size to 100 women per group (total N=200). We expect this magnitude of difference based on previous findings from an observational study by Hancerliogullari et al in 2018 which noted a 19.9% screen positive rate in patients who reported eating within 6.5 hours of the 1 hour GTT versus 48.6% who ate at greater than or equal to 6.5 hours from the test.

We conducted an intent-to-treat analysis to compare the screen positive rate between the fed and fasting groups. The primary and secondary outcomes were assessed using Fisher's exact test. Baseline characteristics between the two groups were compared using Fisher's exact test, and Mann-Whitney-Wilcoxon test was used for continuous variables. Multivariable regression modeling would be used for any imbalance between the treatment groups. Differences were considered statistically significant at $P<0.05$ and analyses was conducted in R (R Core Group, Vienna, Austria).