Final Statistical Analysis Plan

G3. Data Analysis Plan

G3-1. Overview

Data analyses will adhere closely to the CONSORT guidelines [20]. Analyses will follow the intention-to-treat principle in which subjects will be analyzed in the group to which they were randomized, regardless of whether or not they received the assigned intervention.

G3-2. Primary Analysis

Descriptive statistics will characterize the group of individuals recruited and investigate comparability of the two groups at baseline. Formal statistical testing will be limited to selected baseline characteristics considered to be prognostic factors for the primary outcome [43, 44], such as fetal station at complete cervical dilation, birth weight, and duration of the first stage of labor. The categorical prognostic factors will be compared between trial groups by using the Chi-squared or Fisher's exact tests as appropriate. Distributions of continuous prognostic factors will be assessed by visual inspection of histograms and the Kolmogorov-Smirnov test. The two-group independent t-test will be used to compare normally distributed variables. If variables are not normally distributed, the Mann-Whitney U test will be used to make comparisons between the trial groups.

The primary outcome (spontaneous vaginal delivery) and other categorical secondary outcomes will be compared between trial groups by using the Cochran–Mantel-Haenszel test. The estimates of the common relative risk and confidence intervals associated with the primary and secondary outcomes will be calculated. The Breslow-Day test for homogeneity of the odds ratios between subgroups will be reported as well. Distributions of continuous secondary outcome measures such as duration of the second stage of labor within each site will be assessed by visual inspection of histograms and the Kolmogorov-Smirnov test.

G3-3. Secondary Analyses

We will perform other analyses as needed aimed at obtaining adjusted assessments of treatment effectiveness, adjusting for baseline patient characteristics (covariates). The objectives of these analyses are to estimate the influence of covariates on the outcome and to use covariates to improve the estimated difference between treatment groups [45]. The stepwise logistic regression model stratified by study site will be used to identify and estimate the effect of multiple prognostic factors on the probability of spontaneous vaginal delivery and other categorical outcomes. For continuous secondary outcomes such as duration of the second stage, the mixed model in which study site is treated as a fixed effect will be considered to adjust for prognostic factors. Interaction tests will be used to determine whether the effectiveness of the pushing strategy significantly differs across these subgroups. These analyses will be considered exploratory in nature and will not be viewed as providing confirmatory tests of hypotheses.

The following prespecified stratified and secondary analyses will be conducted:

              A. Primary Aim

The following prespecified subgroup analyses will be conducted:

1. Study site

2. Fetal station at complete cervical dilation (high versus low)

49   3. Fetal position at complete cervical dilation (occiput-anterior versus occiput-posterior)

50   4. Duration of delay prior to pushing (<30 min. versus 30 – 60 min. versus >60 min.)

51   5. Maternal age (<35 years versus ≥35 years)

52   6. Maternal Race (Black versus White versus Other)

53   7. Obesity (Obese versus non-obese)

54   8. Birthweight (<3200g versus ≥3200g)

55   9. Fetal sex (male versus female)

56   10. Pushing technique (spontaneous versus directed)

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