Time-to-event power analysis using clinical trial simulations

A power analysis for a clinical trial studying hormonal contraception and HIV acquisition (Gates Foundation)

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Introduction

Some evidence exists that hormonal contraception (HC) may increase the seroconversion hazard, although reports so far are underpowered and inconclusive. Therefore, a clinical trial will be implemented that intends to provide conclusive evidence whether HC increased the hazard or not. To make sure the design of this trial has sufficent power to allow global health decision making, a clinical trial simulations will be implemented to evaluate the design. In this document the results of the clinical trial simulations are reported.

Methods

Clinical trial simulations and power analysis performed in R. An R package was created (*tte_power*) that performs the clinical trial simulations and implements power calculations based on the simulated data.

Results

Discussion

Conclusion

References