

1 OBJECTIVES AND HYPOTHESIS

2 NOTATION AND ABBREVIATIONS

3 STUDY POPULATION / DESIGN / DATA SOURCES

3.1 INCLUSION CRITERIA

Cases:

Controls:

3.2 EXCLUSION CRITERIA

4 MEASUREMENTS AND VARIABLES

4.1 Outcome - efficacy variables

4.2 Exposure covariates

4.3 Mandatory covariates, known confounders

4.4 Additional covariates, potential confounders

4.5 Effect Modification

5 DATA MANAGEMENT

Analysis datasets and files:

Statistical analysis:

6 STATISTICAL ANALYSES

7 STAFF LIST

First and last author. Others.

REFERENCES