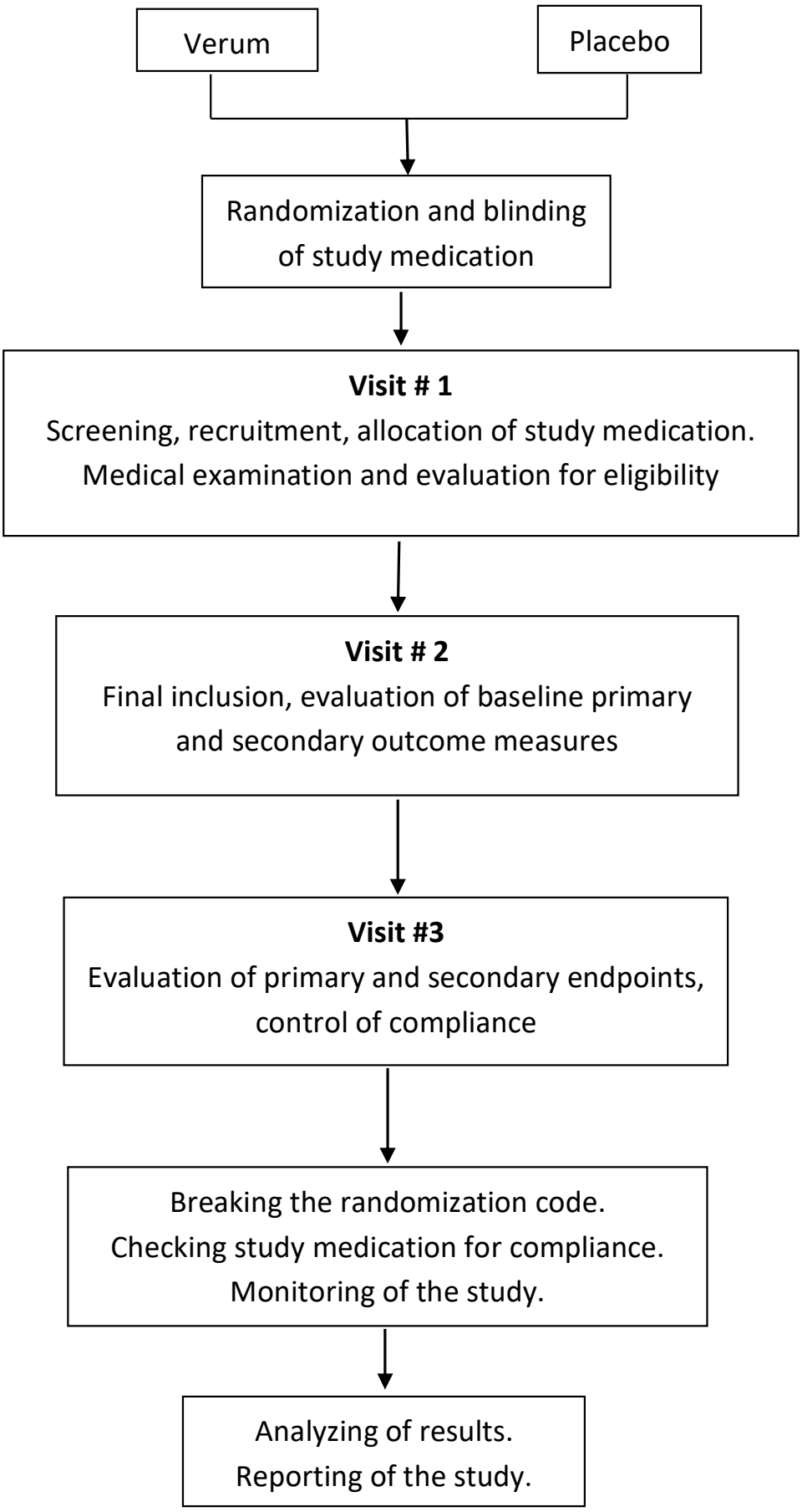
Verum
Placebo
Randomization and blinding of study medication
Visit # 1
Screening, recruitment, allocation of study medication.
Medical examination and evaluation for eligibility
Visit # 2
Final inclusion, evaluation of baseline primary and secondary outcome measures
Visit #3
Evaluation of primary and secondary endpoints, control of compliance
Breaking the randomization code.
Checking study medication for compliance.
Monitoring of the study.
Analyzing of results.
Reporting of the study.