

SHORT TITLE: Orion 4

RESEARCH PROTOCOL TITLE: A double-blind, randomized, placebo controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease

PRINCIPAL INVESTIGATOR: Paul Hinderaker, MD

RESEARCH SPONSOR: The Medicines Company

Clinical Trials.Gov Listing at:

<https://clinicaltrials.gov/ct2/show/NCT03705234?term=inclisiran&rank=6>

STUDY PURPOSE

This study is testing whether the investigational medication called inclisiran, which is given by injection every 6 months, can safely help to prevent heart attacks and strokes in people to have known diseased blood vessels.

STUDY PROCEDURES

There will be 15 visits over about 6 years. During those visits subjects will meet with the study staff. They will receive their study medication injection and healthy lifestyle counseling. At some visits blood may be taken.

ELIGIBILITY CRITERIA FOR SUBJECTS

Must be willing to sign Informed Consent and comply with study procedures
Must be at least 55 years of age at screening
Must have had a heart attack or stroke or peripheral artery disease
Must be on stable cholesterol lowering therapy

SUBJECT PAYMENT

Subjects will be compensated \$25 for each completed study visit.

RESEARCH LOCATION AND CONTACT PERSON

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