

Safety and Efficacy of Low Dose Colchicine in Patients With Statin Intolerance: the LODOCO STINT Pilot Study

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* History of statin intolerance (As defined by the NLA 2023 guidelines) Patients who have experienced one or more adverse effects associated with statin therapy, which resolves or improves with dose continuation or reduction * Stable dose of lipid-lowering regimen (statin or non-statin) for at least one month * Patients able to provide informed consent. * Aged 18 to 80 will be enrolled in the study.

Exclusion Criteria:

* Known hypersensitivity to colchicine, current use of colchicine or other anti-inflammatory medications. * Renal impairment (eGFR \leq 45 mL/min/1.73 m²) * Transaminitis (ALT or AST \geq 3 times upper limit of normal) * Cirrhosis * Severe Heart Failure * Active cancer or currently on chemotherapy * Irritable Bowel Syndrome, Inflammatory Bowel Disease (Crohn's or Ulcerative Colitis) or other diarrheal related GI pathologies * Active infection * Autoimmune or inflammatory condition * Pregnancy or breastfeeding.

Conditions & Interventions

Interventions:

DRUG: Low-dose colchicine at 0.5mg daily, OTHER: Placebo

Conditions:

Statin Adverse Reaction

Keywords:

statin intolerance

More Information

Contact(s): Emily Federmann - Emily.Federmann@vcuhealth.org

Principal Investigator:

Phase: PHASE1

IRB

Number:

System ID: NCT06874192

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