

COCOA

Status: Recruiting

Eligibility Criteria

Age: 18 Years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Age 55 and older 2. Presence of peripheral artery disease (PAD). PAD will be defined as either an ABI \leq 0.90 at baseline or vascular lab evidence of PAD or angiographic evidence of PAD.

Exclusion Criteria:

1. Unable to tolerate study pills 2. Inability to walk or requiring walker to ambulate

Conditions & Interventions

Conditions:

Peripheral Artery Disease

Keywords:

cocoa, cocoa flavanols, intercede, pad, peripheral artery disease, prove

More Information

Description: Among people with peripheral artery disease (PAD) age 55 and older, we will test the hypothesis that PAD participants randomized to cocoa flavanols will have greater improvement or less decline in six-minute walk distance at six-month follow-up, compared to those randomized to placebo. We will randomize 190 participants (32 in Minnesota) with PAD age 55 and older to one of two groups for six months: cocoa flavanols vs placebo. Our primary outcome is change in six-minute walk distance at six-month follow-up. Secondary outcomes are six-month change in maximal treadmill walking distance, Actigraph-measured physical activity, whole body oxygen consumption, measures of nitric oxide (brachial artery flow-mediated dilation (FMD)), calf muscle endothelial nitric oxide synthase (eNOS) and phosphorylated eNOS, calf muscle perfusion (measured by magnetic resonance imaging (MRI)) and calf muscle characteristics (measured by calf muscle biopsy). To achieve our specific aims, we will randomize 190 participants age 55 and older with PAD to one of two groups: cocoa flavanols vs placebo. Participants will be followed for seven months.

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Phase: NA

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