

# Investigation of Metformin in Pre-Diabetes on Atherosclerotic Cardiovascular Outcomes

NCT02915198

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Status	RECRUITING
Phase	Phase 4
Sponsor	VA Office of Research and Development
Enrollment	7,410 participants

## Key Eligibility Criteria

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### Inclusion (16)

- Pre-diabetes: This condition is fulfilled by HbA1c of at least 5.7%, but less than 6.5%; or two measurements of fasting plasma glucose (on separate days) of 100-125 mg/dL; or a 2-hour plasma glucose level of 140-199 mg/dL following a 75 g glucose load oral glucose tolerance test.
  - Established atherosclerotic cardiovascular disease: Qualifying participants must have evidence of atherosclerotic disease in at least one of the following vascular beds: coronary, cerebrovascular, or peripheral arterial circulation.
  - Coronary artery disease is fulfilled by at least one of (1), (2), or (3):
  - History of myocardial infarction at least one month prior to randomization.
  - History of percutaneous coronary intervention or coronary artery bypass surgery at least one month prior to randomization.
- ... and 11 more (see full listing online)

### Exclusion (18)

- Treatment with metformin or other anti-diabetic medication within 12 months of randomization. Note: In the absence of a diagnosis of diabetes, inpatient treatment with insulin or treatment with an SGLT2 inhibitor (e.g., for heart failure) or a GLP-1 receptor agonist (e.g., for obesity) is not exclusionary.
  - Treatment with systemic glucocorticoids within 3 months of randomization
  - Fasting plasma glucose greater than 130 mg/dL measured between screening and randomization visits, or any plasma glucose 180 mg/dL or HbA1c 7.0% measured within 12 months of randomization.
  - Total CO2 below the local laboratory lower limit of normal on most recent blood chemistry panel
  - Current treatment with cimetidine, vandetanib, or a systemic treatment with a carbonic anhydrase inhibitor.
- ... and 13 more (see full listing online)

## Locations (40 total)

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Phoenix VA Health Care System, Phoenix, AZ, Phoenix, Arizona, United States  
Southern Arizona VA Health Care System, Tucson, AZ, Tucson, Arizona, United States  
Central Arkansas VHS John L. McClellan Memorial Veterans Hospital, Little Rock, AR, Little Rock, Arkansas, United States  
... and 37 more locations

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<https://clinicaltrials.gov/study/NCT02915198>

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