



Pre-diabetes is a mild elevation of blood sugar that can lead to diabetes. Pre-diabetes increases the risk of heart attack or stroke.

Metformin is a common drug approved by the Food and Drug Administration to treat diabetes, but it is not currently approved to treat pre-diabetes.

The **VA-IMPACT study** is determining if metformin reduces the risk of heart attack, stroke, and blood vessel problems in patients with pre-diabetes.

Participants receive either metformin or placebo pills. Placebo is a pill that looks like metformin but contains no medication. The study will last 3-6 years. Participants will receive compensation.

You can help us answer this important question! Please let us know if you'd like to learn more. Thank you for considering participation in the VA-IMPACT research study.

VA-IMPACT SAVAHCS TUCSON, AZ Punit Goel, MD



FOR MORE
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VA-IMPACT SAVAHCS Tucson, AZ *Research study for Veterans with* **PRE-DIABETES**

**Does metformin
prevent heart
attacks & strokes
in Veterans who
have pre-diabetes?**



*Information for Patients
07/14/2022 (v5.00)*



Veterans Health Administration
Research Development
Improving Veterans' Lives - www.research.va.gov

What are we studying?

The study team is looking for Veterans with **Pre-diabetes**. Pre-diabetes is a mild increase of blood sugar level.

Pre-diabetes can:

- Lead to diabetes.
- Put people at higher risk for complications like heart attack and stroke.

We are trying to find out if treatment with a commonly prescribed drug **Metformin** can reduce those risks in Veterans with pre-diabetes.

Who can join the study?

You might be eligible if:

- Results from a blood test show mildly elevated sugar or hemoglobin A1c levels –**and**–
- You have a history of blood vessel problems in your heart, brain, or legs –**and**–
- You have adequate kidney function.

Benefits of Participation

Reasons you may choose to participate in this study:

- To learn about treatments that could improve your quality of life
- To improve the quality of life of others
- To receive follow-up care by the study team

Risks of Participation

Like any medication, metformin can have risks and side effects.

- Study doctors carefully monitor study participants to reduce risk.
- The study team can explain the risks to you in detail if you want to learn more.

Compensation

You will receive a minimum of \$20 for the Randomization visit and for each study-related lab test. The amount may increase over time **depending on local factors**.

What is involved if I participate ?

Participation is **VOLUNTARY**. You should participate only if:

- You feel comfortable participating in the study after the study team has explained it to you.
- All your questions have been answered by the study team.

If you meet all requirements and agree to participate, you will be prescribed **either** metformin or a placebo. You, your doctors, and the study team will not know if you get metformin or placebo - it will be randomly decided, like a coin flip.

The first 1 or 2 meetings with the study team are either in person or remote and last about one hour. After that, you will have follow-up contacts by phone or video chat lasting about 30 minutes each, 2-3 times per year, up to 6 years.

You will be asked to go to the lab in the hospital or clinic for blood tests, usually once or twice per year.

To confirm that this study is approved or to ask questions about human subjects protections in research, contact the VA Central IRB at 1-877-254-3130