



Vitamin **D** and
type **2** diabetes

diabetes prevention research matters

News and Information for Collaborating Clinical Sites

Reminder: D2d Annual Meeting is Sept. 25th–26th, 2016 in Arlington, VA. Please register before Aug. 12th.

Study Progress [7/1/2016]

Screenings	6396
Baselines	3436
Randomizations	2013 June: 72

Milestones



- On June 27th, 2016, the Omaha VA randomized the **2000th** participant into D2d!
- Over 100 diabetes outcomes have been reported.
- 396 month 24 study visit have occurred.

Meet the D2d study team | D2d individuals, sites, components that make a difference

D2d Site | MedStar Health Research Institute – Baltimore, Maryland

MedStar's Baltimore site is located in the Good Health Center at MedStar Good Samaritan Hospital in Baltimore. The Good Health Center is a unique outpatient department in the hospital, home to a variety of preventive medicine services, as well as diabetes and pre-diabetes clinical research.

Our site investigators, all board-certified endocrinologists, are the backbone of our team. The investigator team is made up of Dr. Vanita Aroda, PI, the Scientific Director and Physician Investigator of MedStar Community Clinical Research Center. The Baltimore based Co-Investigators, Dr. Jean Park and Dr. Adline Ghazi, broaden the team with research and geriatric experience. Theresa Young is Baltimore's primary coordinator; she is a Certified Health Education Specialist with experience in preventive medicine and a master's degree in Health Science. Theresa shares her experience with D2d on the Support and Education Subcommittee. The program manager for Baltimore and Hyattsville, Amy Loveland, is a Certified Clinical Research Coordinator with years of clinical research experience in diabetes. She also holds a master's degree in Counseling Psychology. Kisha Bates is the Research Lab Technician and contributes her excellent experience and perfect skills; she thoroughly enjoys working with her teammates and the participants. This month, the site welcomed Saif Almushhadani, Clinical Research Associate. Saif has extensive medical background and experience which will add to the strength of our team.

MedStar- Baltimore reached 70% of its recruitment goal in May and maintains its motivation and enthusiasm to reach its recruitment goal as soon as possible!



Left to Right: Saif Almushhadani, Theresa Young, Adline Ghazi, MD, Jean Park, MD, Amy Loveland, Kisha Bates

Questions? Please contact D2d Coordinating Center at D2d@tuftsmedicalcenter.org or 617-636-D2d2 (3232)



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An interview with the PI: A.G. Pittas, MD MS

Q: What is the biggest challenge for D2d now?

A: The use of diabetes medications (e.g. metformin) before the diagnosis of diabetes by D2d or by adjudication.

Q: Why is it an issue?

A: The only way to determine whether the intervention works to lower diabetes risk is to realize the required number of diabetes outcomes. Use of metformin can blur the picture. If participants are placed on metformin, their glycemia will improve and they may not develop diabetes, i.e., there will be less than the needed number of diabetes cases. Furthermore, if vitamin D works as hypothesized, then more participants on placebo will be put on metformin (since they are progressing faster), reducing their diabetes risk, thereby preventing detection of a risk difference between D and placebo.

Q: What is the best way to prevent this?

A: **Assess, educate, communicate and reinforce.**

During the consent process, we need to **assess** the participant's willingness to comply with the study protocol, **which calls for not using a diabetes medication unless diabetes is diagnosed**, and her openness to have the study team communicate with her PCP. If the participant expresses hesitation, it must be addressed then.

Educate participants and their PCPs on the rationale of the study and how the use of Metformin prior to the diagnosis can derail the study. It is also important to **educate** PCPs about the study protocol ideally before randomization and during the study.

Participants should be encouraged to **communicate** with study staff outside of study visits, especially when they are prescribed new medications.

The study, via the portal, provides multiple tools to **reinforce** and remind participants and PCPs about the study, including:

- Study pamphlet: give it to the participant at each visit and point out where the information on diabetes medications is and your phone number.
- D2d appointment cards have study reminders.
- Letter templates (see updated versions in MOP 17 for submission to IRBs).

Q: How are you going to celebrate the end of recruitment?

A: That is going to be a surprise!

D2d Retention Swag



D2d-branded mementos are given to participants at designated visits to promote retention and a healthy lifestyle.