Vitamin D and type 2 diabetes
diabetes prevention research matters

News and Information for Collaborating Clinical Sites

Study Progress [4/1/2015]

Screenings	3177
Baselines	1708
Randomizations	**958**

March 68

Preparing your Continuing Review submission? If you need these from the CC -

- Demographics
- Adverse events
- Protocol deviations

Please let us know!

Protocol version 1.7 is now available to submit to your IRB

This new version includes a provision allowing screening glycemia labs (i.e. FPG, HbA1c) to be analyzed either at the site local laboratory or at the Central Laboratory. **Sites are strongly encouraged to use the Central Laboratory for the analysis of HbA1c and FPG.** The goal is to reduce the discrepancy between sites' local labs and the Central Lab, and thereby increase the baseline success rate. While this may add a few days to the screening process, it will save a great deal of time and resources in the long run by reducing unsuccessful baseline visits. Sites using the Central Laboratory to analyze FPG and HbA1c will use a **new and improved** study-wide default algorithm – *please see next page* for illustration.

➢ Protocol v1.7 is available in the Protocol section of the D2d portal.

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

D2d Site | Duke University, Durham, NC

The D2d study team at Duke is part of the Duke Primary Care Research Consortium (PCRC), which conducts a variety of clinical trials in primary care practices throughout the Duke University Healthcare system as part of the Duke Clinical Research Institute. The PCRC was formed in 1997 by Dr. Rowena Dolor, who also serves as co-PI for our D2d site. Our active D2d study team includes PI Dr. Ranee Chatterjee Montgomery, Clinical Trial Assistants Erica Suarez and Stephanie Smith, and Study Coordinator Kathy Chmielewski. Dr. Chatterjee is a primary care provider at one of our Duke Internal Medicine practices, in addition to her work in clinical research. She is also a busy mom of two daughters, one of whom recently became a teenager! Erica and Stephanie are our recruiters. Stephanie has one other BIG project she is working on — she is expecting her first baby on May 2nd! Erica is a UNC graduate who has been working with the Duke team for nearly 4 years now. Kathy has been with the PCRC since 1999 and currently works exclusively on D2d.

L to R: Dr. Rowena Dolor, Stephanie Smith, Dr. Ranee Chatterjee Montgomery, and Kathy Chmielewski

March has been busy with D2d, but we have still managed to enjoy March Madness. Durham is in the middle of what is known as Tobacco Road in the world of NCAA basketball, with the NCSU Wolfpack, the UNC Tar Heels, and the Duke Blue Devils all making the Sweet Sixteen this year. And of course Duke went on to win it all to become 2015 NCAA Men's Basketball Champions – CONGRATULATIONS DUKE!!

Questions? Please contact D2d Coordinating Center at d2d@tuftsmedicalcenter.org or 617-636-D2d2 (3232)

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From the DSMB report (study progress as of 1/31/2015):

- Recruitment is at 34% of target (814 out of 2382)
- Retention: 4 participants in total have gone "off study", i.e. withdrew consent (1 since last report)
- Baseline characteristics:
  - 49% women
  - 37% non-white
  - 8.8% Hispanic or Latino
  - Age = 59 years
  - BMI = 31.9
- Visit completion >96%
- Outcomes: 9 total (7 since last report)
- No participants have been unmasked
- A total of 20 SAEs have been reported (12 since last report)
- A total of 342 AEs have been reported (159 since last report)
- There have been no UAPs

D2d Welcomes Denver

The University of Colorado Denver and the Denver VA Medical Center have recently joined the D2d Study and have already started recruiting participants. Dr. Neda Rasouli is the site Principal Investigator. Welcome to the D2d Study Team!

D2d Participant Features

We are still seeking stories from your participants to include in future editions of the D2d Participant Newsletter and website. Please ask your participants if they would like to share a photograph, story, recipe, or an experience they have had while participating in the study.

Example of the new study-wide default algorithm for determining eligibility to proceed to baseline. **Always refer to MOP 6 Appendix 10 for the current version! **

If HbA1 (%) is:	FPG (mg/dL) must be within this range
5.6	116 - 120
5.7	112 - 118
5.8	108 - 115
5.9	103 - 113
6.0	98 - 111
6.1	94 - 109
6.2	89 - 106
6.3	85 - 104
6.4	80 - 102
6.5	76 - 99