

Background

Type 1 diabetes is an autoimmune disease which generally begins during childhood. It occurs when the immune system — there to help your body fight infection — mistakenly attacks your insulin-producing cells. When these cells are destroyed, your body can no longer make insulin. This is how type 1 diabetes happens.

The Nutritional Intervention to Prevent Type 1 Diabetes study will help us learn more about a dietary substance called docosahexaenoic acid (DHA), an Omega-3 fatty acid. DHA is a natural ingredient found in a mother's breast milk and in various foods. It may be important to the growth of a healthy baby. This research is being done as a pilot study, which is a "test run" to find out if it is possible to do a larger study.

Who can participate

- **Pregnant women in their 3rd trimester** (more than 24 weeks) may enroll in the study if the baby they are expecting has a relative (mother, father, sister, brother, half-sister, or half-brother) with type 1 diabetes*
- **Babies up to five months old** may also be enrolled in the study if they have a relative with type 1 diabetes*

*Babies will require a blood test to determine eligibility.

Type 1 Diabetes TrialNet

Researchers conducting this study are part of a larger group called Type 1 Diabetes TrialNet, an international network of centers dedicated to the study, prevention, and early treatment of type 1 diabetes.

To learn more about this study or other TrialNet studies, call toll free

1-800-HALT-DM1 (1-800-425-8361)

You can also learn more at

www.diabetestrialnet.org

All shared information will remain confidential.



TrialNet Sponsors



National Institute of Diabetes & Digestive & Kidney Diseases
NATIONAL INSTITUTES OF HEALTH



National Institute of Allergy and Infectious Diseases
NATIONAL INSTITUTES OF HEALTH



National Institute of
Child Health and Human
Development (NICHD)



National Center for
Research Resources



Juvenile
Diabetes
Research
Foundation
International

dedicated to finding a cure



American Diabetes Association®

Cure • Care • Commitment®

Nutritional Intervention to Prevent (NIP) Diabetes



A Research Study for Infants at Increased Risk for **Type 1 Diabetes**

Type 1
Diabetes
TrialNet

What does participating involve

If pregnant, you will take four capsules a day during your third trimester. If nursing, you will also be asked to take four capsules a day.

- The capsules will contain either DHA or an ingredient that does nothing at all called a placebo.
- Neither you nor the study staff will know if you are taking the capsules with DHA or the capsules with placebo.

If your baby is on infant formula, you will be asked to use formula provided by the study. All study formula will contain some DHA.

You and your baby will need to make regular visits to the study site.

- We will collect a sample of your baby's blood.
- We will ask about your baby's diet and yours (if you are pregnant or nursing).
- If you are nursing, you will need to bring in a sample of your breast milk.
- We will also ask other health questions.

It is anticipated that babies will participate in the study for at least one year.

Why participate

- You might learn whether your baby is at risk for getting type 1 diabetes.
- If this study is successful, your baby might become part of a larger study to determine if type 1 diabetes may be prevented.
- You and your baby will be contributing to diabetes research.

Nutritional Intervention to Prevent Type 1 Diabetes

For more information, contact one of the participating centers:

California

Childrens Hospital
Los Angeles
Los Angeles, CA
(888) 835-3761

Children's Hospital of
Orange County
Orange, CA
(714) 532-8613 or
(714) 532-8642

University of California,
San Francisco
San Francisco, CA
(415) 502-8640

Indiana

Indiana University
Riley Hospital for Children
Indianapolis, IN
(866) 230-8486

Iowa

University of Iowa
Children's Hospital of Iowa
Iowa City, IA
(866) 309-0837

Massachusetts

Joslin Diabetes Center
Beth Israel Deaconess
Medical Center
Boston, MA
(617) 732-2647

Minnesota

University of Minnesota
Minneapolis, MN
(612) 625-7931

Missouri

The Children's Mercy Hospital
Kansas City, MO
(816) 983-6529

Utah

University of Utah
Utah Diabetes Center
Salt Lake City, UT
(801) 587-3972

