APPROVED
FEB 26 2009
IRB: 00004971

CENTER FOR AUTISM AND RELATED DISORDERS IRB
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: Study of Vitamin D to Prevent Autism in Newborn Siblings

INVESTIGATORS: Doreen Granpeesheh, PhD. (818) 345-2345; Gene Stubbs, M.D., P.C., (503) 245-2719; John Green, M.D., (503-722-4270); and Kathy Henley (503) 351-9255.
(See additional participating physicians from other geographic areas, page 4)

PROTOCOL # 1-08-002

PURPOSE

You are being asked to participate in a research study along with your newborn baby. The purpose of this study is to determine if Autism can be prevented in the newborn sibling of a child(ren) with autism through the use of Vitamin D3.

PARTICIPANTS

You and your anticipated or newborn child have been selected to participate because one or more of your children has been diagnosed with autism, and you (the mother) are either pregnant or intending to get pregnant.

PROCEDURES

Upon agreeing to participate in the study, the mother will be given Vitamin D3 at the dose of 5000 IU daily during pregnancy and 7000 IU during breast feeding. If you decide not to breast feed or for some reason are unable to breast feed, your infant will be given 1000 IU daily. During the second year, the child will be given 2000 IU daily. When the infant becomes 18 – 24 months, the mother will be given a screening questionnaire or receive a phone interview to determine if the child is developing symptoms of autism. If the screening is positive for autism symptoms, the child will be scheduled for a formal evaluation for autism. This will include an interview with the mother and/or father and an observation of the child. Parents will be informed of the results of the study at the end of the study when all of the results are tallied. Blood will be withdrawn from a vein in the arm of the mother before taking Vitamin D and during treatment with Vitamin D for a total of two blood draws for the mother and one blood draw for the child. The blood will be drawn from the child at 1 year of age. There will be at least three visits to the Evergreen Center in Oregon City, Oregon or to participating physician's offices.

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RISKS

There are no known risks from Vitamin D except at much higher doses such as 50,000 IU. Hypercalcemia may develop at very high doses. The doses prescribed have been determined to be safe by the Food and Nutrition Board, of the Institute of Medicine. There is a small risk of bruising at the site of the blood draw.

BENEFITS

The benefit in participating in this research project is not known. It is possible that there will be no benefits or this study may lead to information which helps other families with autism.

CONFIDENTIALITY

Your identity will be protected to the extent allowed by law. You or child will not be personally identified in any reports or publications that may result from this study. Only the CARD Institutional Review Board and the investigators will have access to the data. The data and consent forms will be stored securely and separately in a locked room in the co-investigator's office for the duration of the study. Once the study is completed, the data and consent forms will be transferred to a locked location in the office of the primary investigator, for 3 years and then will be destroyed.

COSTS/COMPENSATION

There will be no cost to you except for transportation to the site and back, nor will there be any compensation for participating in the study. Dr. Stubbs, Dr. Green, Kathy Henley, and any of the other participating physicians will not be able to provide compensation or free medical care for an unanticipated injury sustained as a result of participating in this research study.

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RIGHT TO REFUSE OR WITHDRAW

Participants reserve the right to refuse to participate or withdraw from the study at any time without penalty. If the study design or use of the data is to be changed, you will be so informed and your consent re-obtained. Participants will be informed of the results of the study at the end, after the results have been analyzed.

QUESTIONS

If you have any questions, please ask us: Gene Stubbs, M.D., P.C., (503) 245-2719; John Green, M.D., (503-722-4270); or Kathy Henley (503) 351-9255. If you have additional questions later, contact Cathy Vizconde, PhD. (818) 345-2345; or your participating physician. You may also report (anonymously, if you so choose) any complaints or comments regarding the manner in which this study is being conducted to the CARD IRB at (818) 345-2345 or by addressing a letter to the Chair of the Board, c/o CARD IRB, 19019 Ventura Blvd., Tarzana, CA 91356.

CLOSING STATEMENT

MY SIGNATURE BELOW INDICATES THAT I HAVE DECIDED TO VOLUNTEER AND TO VOLUNTEER MY CHILD AS A RESEARCH PARTICIPANT AND THAT I HAVE READ, I UNDERSTAND, AND I HAVE RECEIVED A COPY OF THIS CONSENT FORM.

SIGNATURE OF PARTICIPANT (OR LEGALLY RESPONSIBLE PERSON) DATE

SIGNATURE OF INVESTIGATOR DATE

SIGNATURE OF WITNESS DATE

Parent/Guardian's Initials: _____ Date: _____ (mm/dd/yy)

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Additional Research Sites and Participating Physicians:

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