FAZST

FOLIC ACID AND ZINC SUPPLEMENTATION TRIAL

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A Message from your FAZST Study Officers

The FAZST research team would like to extend a huge thank you to all the participants who are enrolled in this important study. I am one of your FAZST Study Officers, Sunni Mumford. I am an investigator at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) in Bethesda, Maryland. I am originally from Utah and went to Utah State University. Go Aggies!

Dr. Sunni Mumford

Your participation in FAZST is important in helping understand how fertility can be improved with dietary supplements. Zinc and folic acid are safe supplements that are important in reproduction and available evidence suggests that they may improve sperm quality. Your participation in this landmark clinical trial will provide the highest quality of research evidence in understanding the relationship of diet and male fertility.

I am one of your FAZST Study Officers, Enrique Schisterman. I am the Epidemiology Branch Chief at the NICHD and have been the Principal Investigator in other large clinical trials. I am originally from Argentina and have lived in the Washington, D.C. area for a number of years with my wife and two daughters.

Dr. Enrique Schisterman

I am happy to highlight that we have conducted over 2000 participant follow up visits! Your participation in the follow up visits is essential in ensuring a successful clinical trial. Fertility research often focuses on female fertility. We believe that understanding factors that affect male fertility is an equally important focus that has the potential for major discoveries and future impact.

Please feel free to contact us with any questions or concerns at studycontact@emmes.com. Also, please feel free to share our information with others who may be interested within our study communities.

What is the value of clinical trials for finding health benefits of dietary supplements?

One of the major discoveries related to pregnancy in the 20th century was that a folic acid supplement taken by women who were trying to get pregnant reduced the risk of neural-tube birth defects in their babies. So, when we see a news report or a web site that suggests that taking a supplement might make us healthier, why not just take supplements? For one thing, the dose of the supplement can make all the difference in its health effects. Scientific studies are needed to measure the dose precisely and determine how much to use to get a desired health effect. Sometimes a trial leads us to understand that a supplement does not have the benefit it is thought to have. Below we explain features of FAZST that are essential to producing useful results for future couples who are trying to grow their family.

"Scientific studies are needed to measure the dose precisely and determine how much to use to get a health effect."

Why is it important for the trial to be randomized?

A randomized, double-blind trial means that the assignment of receiving the dietary supplement or placebo is by chance, and the participants and investigators do not know who received the dietary supplement. This is important because people who actively choose to take supplements generally differ from people who don't take supplements in their habits and their health histories. Your study supplement contains either zinc and folic acid or inactive ingredients. Whether you received the active ingredients or inactive placebo was determined by a chance, automated process called randomization. When the decision of who takes the active supplement is made by chance, people who get the active supplement are then comparable to the people who don't, based on known and unknown risk factors.

Why is completing study tasks and visits so important?

Filling out questionnaires and attending study appointments is no small matter. We know this requires your valuable time, as well as patience, careful thought, and planning- which we greatly appreciate. The study requires detailed information about your diet and lifestyle, updated over time. Thank you for your patience when providing study information that you may have already provided for your treatment. We have streamlined the data collection wherever possible and will continue to do so. Complete information on all participants ensures that we are collecting accurate, meaningful data. When we compare fertility in participants assigned to the active supplement with participants assigned to the inactive placebo, we hope to measure the effect among people who took the supplement every day versus those who did not take it at all. Keeping study appointments and completing your questionnaires are also important for monitoring your safety throughout the trial.

Thank you again! The next page provides you some tips for success!

Helpful hints

- Store your pill bottle in a place where you can grab it during your morning routine, such as on top of your dresser, next to the coffeemaker, or with your keys. Please keep it out of the bathroom because heat and moisture can degrade the supplements.
- Set a daily reminder on your phone or computer.
- Place a note on your bathroom mirror or refrigerator door.

Finding time to fill out daily journals and questionnaires

- Set aside a regular time each day to complete your journal at www.fazstpa.com.
- Create a quick home screen link on your phone to the www.fazstpa.com log-in screen. You may ask your study staff for help setting this up.
- The 24-hour dietary recall (the ASA24) must be completely finished before midnight the day you start filling it out, so if you complete it in the evening, start early enough so that you can complete it before midnight. This survey should take 30-45 minutes. Though the questions are very detailed, *just do your best* estimating types and amounts of foods.

Rescheduling an appointment

Please keep track of your upcoming appointments and reschedule early if you anticipate a scheduling conflict. Each study appointment must take place in a 14-day window, a time-frame based on the science of male reproduction.

To reschedule, contact your study coordinator:

- UTAH: Denise Lamb
  - Salt Lake City (801) 585-2585
  - South Jordan (801) 213-5998
  - Orem (801) 234-8572
- IOWA: Karen Summers (319) 356-8862 or by email FAZST@uiowa.edu
- ILLINOIS: LaShante Griffin (312) 503-4118

New health issue? Tell us about it!

Our number one priority when conducting a randomized clinical trial is your safety. We have careful measures in place to make sure that the supplements you are receiving are not causing harm. In order to ensure your health and safety, it is essential that you tell us about all health related issues, no matter how small and unimportant they may seem. This includes letting your study coordinator know about unrelated planned medical procedures, emergency room visits, new medications, and new diagnoses. It may be as simple as having a cold for a few days. Please go ahead and let us know!

Study Site Focus: University of Utah

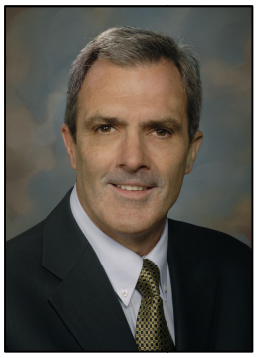
FAZST is up and running thanks to the hard work and clinical expertise of the University of Utah research team. FAZST's longest-running study site has enrolled 748 participants at clinical centers in Salt Lake City, Orem, and South Jordan. If you are a participant from Utah, you may have met the infertility specialists, Dr. Peterson and Dr. Johnstone. Both doctors oversee FAZST closely to uphold patient safety and meet the study's scientific objectives.

C. Matthew Peterson, M.D., Co-Principal Investigator

Dr. Peterson sees patients in reproductive endocrinology, directs the IVF program at the Utah Center for Reproductive Medicine, and serves as Chair of the Department of Obstetrics and Gynecology at the University of Utah. He has been the Principal Investigator for numerous clinical trials and clinical studies. Additionally, he is the co-editor of a textbook on scientific, medical, and management issues in reproductive endocrinology and infertility.

Erica B. Johnstone, M.D., Co-Principal Investigator

Dr. Johnstone's clinical practice focuses on reproductive endocrinology, infertility of all types, reproductive endocrine disorders, and hormonal disturbances in children and adolescents. In addition to clinical care, she has conducted clinical research as a medical resident, fellow, and attending physician. During her medical residency, she completed training in clinical research and received a master's degree in Health Sciences. She received the Resident Achievement Award from the Society of Laparoendoscopic Surgeons in 2005.



Dr. C. Matthew Peterson

Dr. Erica B. Johnstone

Participating FAZST Clinical Sites

This past fall the FAZST study welcomed two new clinical sites, the University of Iowa in Iowa City, IA, and Northwestern University in Chicago, IL. The University of Iowa has been actively enrolling since October 2014. We welcome Iowa participants to the study! The study team at Iowa includes Dr. Brad Van Voorhis, Dr. Ginny Ryan, and Research Coordinator, Karen Summers. Karen can be reached at (319)356-8862 or FAZST@uiowa.edu

UNIVERSITY OF IOWA HOSPITALS & CLINICS
University of Iowa Health Care

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

Northwestern University recently began enrolling participants. The Northwestern study team includes Dr. Jared Robins and Research Coordinator, LaShante Griffin. LaShante can be reached at (312) 503-4118 or FAZST@Northwestern.edu. We are excited to welcome both sites on board!