FOLIC ACID AND ZINC SUPPLEMENTATION TRIAL

FAZST

A MESSAGE FROM YOUR FAZST STUDY OFFICERS

The FAZST research team offers a sincere thanks to the **1,329 participants** who have enrolled in this innovative study over the past 2.5 years! Your hard work in FAZST is important in understanding how fertility can be improved with dietary supplements. This is a landmark clinical trial that will provide the highest quality of research evidence. Thank you for being our partner in discovering new ways to improve fertility treatment. Nearly all participants successfully complete their full participation requirements, a testament to your dedication and the outstanding support from our exceptional study staff.

We are happy to highlight that we have conducted over 2000 participant follow-up visits! We recognize you all lead busy lives and sincerely appreciate your commitment to attend follow-up visits -- attendance has been excellent. Your participation in the follow-up visits is essential in ensuring a successful clinical trial. Although fertility research often focuses on female fertility, we believe that understanding factors affecting male fertility is an equally important focus that has the potential for major discoveries and future impact.

FAZST grew by leaps and bounds in 2015, activating enrollment at our two new clinical sites at the University of Iowa in Iowa City, IA and Northwestern University in Chicago, IL. University of Utah remains FAZST's longest-running study site with Utah clinical centers in Salt Lake City, Orem, South Jordan, and a new clinical center in St. George at Southwest Fertility Clinic. University of Iowa also added a clinical center at the UI-Quad Cities Clinic staffed by Dr. Jessica Kresowik. We are grateful for the tremendous efforts and expertise from our study officers and staff, and we hope they have made your FAZST experience as smooth and rewarding as possible.

As is standard practice for all clinical trials, an independent Data Safety and Monitoring Board reviewed and approved the study's record of safety, enrollment, and study completion. This was part of the Board's routine study oversight that ensures the study team is fulfilling its responsibilities to you, the participants.

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.

Drs. Sunni Mumford & Enrique Schisterman
FAZST Study Officers
Eunice Kennedy Shriver National Institute of Child Health and Human Development

NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development

CONTACT INFORMATION UNIV OF UTAH SITES

Email to reach any of the four Utah study sites: fazst@hsc.utah.edu or fertilitytrial@hsc.utah.edu

The Utah Center for Reproductive Medicine
(801) 587-1180
675 Arapeen Way, Suite 205
Salt Lake City, UT 84108
fertilitytrial@hsc.utah.edu

South Jordan Health Center (Daybreak) University of Utah, Fertility Clinic
(801) 213-5998
5126 West Daybreak Parkway
South Jordan, UT 84095
fertilitytrial@hsc.utah.edu

Parkway Health Center, Orem University of Utah, Fertility Clinic
(801) 234-8572
145 West University Parkway
Orem, UT 84058
fertilitytrial@hsc.utah.edu

Southwest Fertility Clinic, St. George Dixie Regional
(435) 688-4284
544 South 400 East
St. George, UT 84770
eva.livingston@imail.com

Study Coordinator:
Denise Lamb, RN, CCRP
University of Utah, School of Medicine
Department of Obstetrics and Gynecology
30 North 1900 East, Room 2B296
Salt Lake City, UT 84132
(801)585-2585
denise.lamb@hsc.utah.edu

Reproductive Endocrinologists:
C. Matthew Peterson, MD
Erica Johnstone, MD
Jessie Dorais, MD
Andrew Moore, MD
Jim Hotaling, MD
Megan Link, MD
William Keye, MD

CONTACT INFORMATION UNIV OF IOWA SITES

University of Iowa Center for Advanced Reproductive Care
(319) 356-8862
200 Hawkins Drive, 31340 PFP
Iowa City, IA 52242
FAZST@uiowa.edu

University of Iowa Women's Health Quad Cities
(563) 355-2244
3385 Dexter Court, Suite 110, Building 3
Davenport, IA 52807

Study Coordinator:
Karen Summers, MPH, CHES
(319) 356-8862
200 Hawkins Drive, 31340 PFP
Iowa City, IA 52242
FAZST@uiowa.edu

Reproductive Endocrinologists:
Elizabeth Graf, PA-C
Brad Van Voorhis, MD
Ginny Ryan, MD
Craig Syrop, MD
E. Hakan Duran, MD
Jessica Kresowik, MD (Quad Cities)
Erica Munch, MD
Josh Kapfhamer, MD
Rachel Mejia, DO

CONTACT INFORMATION NORTHWESTERN UNIV SITE

Northwestern Medicine Reproductive Endocrinology and Infertility
(312) 503-4118
259 East Erie Street
Suite 2400
Chicago, IL 60611
fazst@northwestern.edu

Project Manager:
Mallory Snyder, MPH
(312) 503-4118
259 East Erie Street
Suite 2400
Chicago, IL 60611
fazst@northwestern.edu

Reproductive Endocrinologists:
Staci Gorson, FNP-BC
Jared Robins, MD
Edmond Confino, MD
Ralph Kazer, MD
Mary Ellen Pavone, MD
Erica Marsh, MD
Randall Barnes, MD
Serdar Bulun, MD
Magdy Milad, MD

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. Helpful Tips

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. The ASA 24 can be accessed at https://asa24.nci.nih.gov/.

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 few days. Please go ahead and let us know!

Thank you for contributing to the success of FAZST

You may be wondering: ***what are the results of the study so far?*** In fact, the investigators and staff have not analyzed the data as it comes in – and for good reason! Before starting the study, we carefully planned out the analysis and the number of participants we would need in the study in order to find the most valid results. We take this so seriously that study staff and investigators cannot access information on who took the supplement and the placebo until after the study ends. When the study reaches its target number of participants, we will stop enrollment and prepare the data for a timely analysis. Results will then be shared with all participants. Analyzing the data from fewer than the target number of participants undermines our ability to produce valid results. As such, we are maintaining the highest scientific integrity of the study in order to best inform doctors and couples trying to conceive in the future.

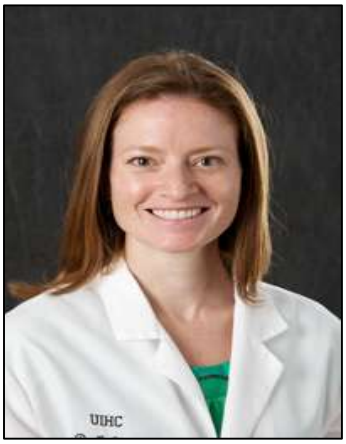
Study Site Focus: University of Iowa & Northwestern University

We are thrilled to have the expertise of the Reproductive Endocrinology and Infertility (REI) staff at the University of Iowa and Northwestern University join FASZT.

This includes all members of the team including research coordinators, administrative staff, medical fellows and residents, laboratory staff, and REI physicians including the principal investigators, Dr. Ginny Ryan and Dr. Brad Van Voorhis at University of Iowa and Dr. Jared Robins at Northwestern University. They are working hard to uphold patient safety and help FAZST succeed in its mission to help couples undergoing treatment for infertility.

Dr. Van Voorhis is a Professor of Obstetrics and Gynecology, Director, Division of Reproductive Endocrinology and Infertility and Executive Vice Chair of the Department of Obstetrics and Gynecology at the University of Iowa, Iowa City. In addition to a full clinical practice and serving as co-principal investigator of FAZST, Dr. Van Voorhis serves in multiple leadership roles in national societies and committees in reproductive medicine and has co-authored over 100 peer reviewed scientific articles!

Brad J. Van Voorhis, M.D.
Site Principal Investigator



Ginny L. Ryan, M.D. M.A.
Site Principal Investigator

Dr. Ryan is an Assistant Professor of Obstetrics and Gynecology- Reproductive Endocrinology and Infertility and serves as co-principal investigator of FAZST. Dr. Ryan has a special interest in pediatric gynecology and has a research focus on the treatment of infertile couples and has championed the movement towards single blastocyst transfer in assisted reproduction.

Jared C. Robins, M.D.
Site Principal Investigator

Dr. Jared Robins is the FAZST principal investigator at Northwestern University and is Chief of the Division of Reproductive Endocrinology and Infertility and an Associate Professor in the Department of Obstetrics and Gynecology at Northwestern University Feinberg School of Medicine. Dr. Robins is a nationally renowned fertility expert whose research focuses on optimizing the conditions for embryonic development to improve assisted reproduction.