



TRIGR USA

An NIH-Sponsored Primary Prevention Study for Type 1 Diabetes

TRIGR Tale from Pittsburgh by Elizabeth Oleska

I want to start by thanking the entire TRIGR staff in Pittsburgh for everything you have done to help my son, Logan Alexander, and myself. Without your help throughout the study thus far, I know we would not be where we are in our lives right now. Being a young, single mother, full-time college student, and part-time Assistant Director of a Dementia and Alzheimer's unit, you can imagine things have not been easy. But thanks to all of you, we are making it through our days one at a time. Without the help of the formula provided in the first 6-8 months of Logan's life, all the supporting words and cards, and friendly words of guidance, I know that I might not have made it as far as I have being a mother. However, the most rewarding part of receiving all of this incredible help, is knowing that we have been able to help in making a difference in other's lives in return.



Logan Oleska

Receiving monthly phone calls by the nurses and dietitians not only let us know that others want to make sure things are going well for us, but also that we are cared about. It is a tremendous feeling. Logan is now around the corner from turning 15 months of age, and growing like you would not believe. He is close to 32 lbs and 33" (2' 9") tall! He is running around, learning to speak, and making a huge smile grow wider on my face as every day passes.

I just want to thank all of those who are behind the scenes and on the scenes of making this study run. I admire each and every one of you and thank you from the bottom of my heart for all the differences you are making in my life as well as the lives of others. I know that my son and I have been deeply blessed in becoming a part of this study, and I hope you all know how much of a difference you have made. Thank you again for everything!

1-888-STOP T1D
www.TRIGR.org
www.trignorthamerica.org

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TRIGR Triumphs!

TRIGR is a large multi-center trial investigating both genetic and environmental factors that are related to T1D. Pregnant women are eligible for the study if they themselves have T1D, OR the father of

the baby has T1D, OR a full-sibling to the baby has T1D.

Since May 2002, we have enrolled over 4,000 babies worldwide! In the US alone, we have enrolled

821 families. Of these families in the US, 631 have given birth and 45 percent of the babies are eligible to continue in TRIGR based on their HLA genotype. Our oldest child is three years of age!

Center Spotlight: St. Louis

St. Louis is home to the US TRIGR site #3. The St. Louis TRIGR team is based at the Washington University in St. Louis (WUSTL). The team consists of the following dedicated and talented individuals:

Neil White, MD CDE is a Pediatric Endocrinologist and Professor of Pediatrics and Medicine in the Washington University School of Medicine in St. Louis. He is currently the Co-Unit Leader of the pediatric-based Patient Oriented Research Unit as well as the Director of the Pediatric General Clinical Research Center at Washington University in St. Louis. Dr. White has over two decades of research and clinical care experience and has volunteered as the diabetes summer camp director and physician for numerous years in the St. Louis area. Dr. White is a proud father of two children.



The St. Louis TRIGR Team:
Left to Right: Jackie Jones, Marilyn Tanner, Cheryl Chambliss, Neil White (not shown: Michelle Sadler)

Marilyn Tanner, MHS RD LD is the St. Louis Site TRIGR Study Coordinator and Dietitian. As a Registered Dietitian Marilyn has worked in the

Pediatric Nutrition field for 15 years.

Jackie Jones is the TRIGR study recruiter. Jackie has been and continues to work on several diabetes research studies as a recruiter, and is the study coordinator for a Peer Counseling in Diabetes research study. Jackie is the proud mother of two children.

Cheryl Chamblis, RN MSN APN is a TRIGR study nurse. She has recently joined the TRIGR study and has been doing pediatric nursing for 20 years. Cheryl has worked on several drug studies in the area of diabetes and is the proud mother of three.

Michelle Sadler, RN BSN CDE is a TRIGR study nurse. For several years Michelle has worked on numerous diabetes research studies for Type 1 diabetes and Type 2 diabetes. Michelle is the proud mother of three children.

Nutrition Nibbles: Vitamin D by Marilyn Tanner, MHS RD LD

Vitamin D is a fat-soluble vitamin that helps your body utilize important nutrients such as calcium and phosphorus. This makes bones and teeth stronger and healthier.

Some vitamin D is obtained from sunlight (yes, a little sunshine can be nutritious for you!) as your body synthesizes the active form of vitamin D from precursors in the body when it is exposed to sunlight. Just 5-15 min of sunlight per day on exposed skin (face, hands, and arms) can help you reach your daily vitamin D needs. However, it is still important to use sunscreen when you will be outdoors for more than 15 min. Those living in the north-

ern states should make sure they are getting adequate vitamin D through formula, supplements, or fortified foods. Milk in the U.S. is fortified with vitamin D. It does not occur in milk naturally, but was added in the 1940's to help prevent rickets. If you cannot tolerate milk, some calcium-fortified juices have vitamin D added.

Food	Amount	Vitamin D (IU)
Margarine	1 tsp	20 IU
Egg yolk	1 large	25 IU
Milk (fortified)	8 ounces	100 IU
Salmon w/bones	3 oz	190-535 IU
Fortified Juices	8 oz	Varies - see label

The recommendation for an adequate intake of vitamin D is 200 IU from birth through age fifty. You should speak with your pediatrician to find out if your child could benefit from the use of a vitamin D supplement, especially if your child is exclusively breastfed or if you live in a northern climate where sunlight exposure is limited. Formula-fed infants do not need vitamin D supplements since formula is fortified with vitamin D. As your child starts consuming solid foods, make sure your child's diet is and continues to be nutrient dense. Providing calcium-rich foods and sources of the vitamin will help promote normal bone growth.

Letter from the St. Louis Team

Dear TRIGR families,

The staff and families of US TRIGR site #3 at Washington University in St. Louis, Missouri, hope that you have had a good summer. You can find St. Louis in the middle of a map of the United States along the Mississippi River. St. Louis is truly a mid-western city; we are partly eastern, partly western, partly northern and partly southern, and are the home of the National League Champion St.

Louis Cardinals and the 1999 Super Bowl Champion St. Louis Rams.

Recruiting study participants from multiple countries and continents has been a truly a monumental task, and Washington University in St. Louis is honored to be a part of the TRIGR study family. Now that we are two-thirds (2/3) of the way to the necessary 2,730 babies needed to complete this study and some of the babies in TRIGR are now 3-4 years old, we

should all be proud of what we have accomplished. But, we need about another 1,000 families to join the TRIGR team. Please continue to pass along the word so that more families are aware of TRIGR and have the opportunity to be a part of this important effort.

Wishing you all a happy and productive year, and GO CARDINALS!

Health News: Colic or Study Formula Intolerance? By Barney Softness, MD

Colic is uncontrollable extended crying in a baby who is otherwise healthy and well-fed. All babies cry to some extent, but if a baby cries for >3 hours a day for 4 or more days a week, he/she is considered to have colic. Colic usually starts at 3 weeks of age and peaks at 4-5 weeks of age, then wanes starting at 6 weeks (coincident with early smiles) and is often gone by 12 weeks.

Colic occurs in all cultures and regions of the globe, in formula and breast fed babies and in both sexes equally. Colic appears to be related to the digestive system because of increased gas, apparent abdominal pain and altered bowel habits, but there is little objective evidence to prove this. More likely, colic is a complex combination of temperament and an immature nervous system.

Colic can occur at any time, but is usually worse in the evenings (just when the grownups are getting tired!). Although colic is not thought to be due to pain, the baby looks very uncomfortable. Babies may lift their head, draw their legs up and become very red in the face.

There is no proven cure for colic, but there are several measures that

can help. Different babies are comforted by different measures, and parents should try various methods to see what works. There are many theories that colic is related to what the baby eats - but this doesn't explain why they were asymptomatic for the first 2 weeks. Breast feeding mothers have been encouraged to avoid many foods, such as broccoli, beans and other gas producing foods. Stopping these foods has not been shown to decrease gas in the baby (the gas producing compounds never get into the breast milk). Some dairy or nuts may bother a small percentage of babies - a trial of abstinence and restarting of these foods may be informative. Techniques that reduce swallowed air, such as frequent burping, changing bottles or positions, can often be helpful.

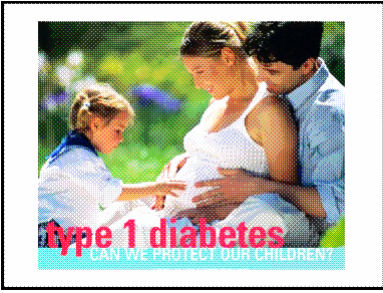
Formula is often blamed for the symptoms of colic. Some babies may be allergic to the protein component of the milk (cow or soy) or they may be unable to absorb the milk sugar (lactose). These conditions can create gas, bloating, loose stools and even vomiting. There may be mucus in the stool and rarely blood. Formula intolerance is usually determined by an elimination diet followed by a re-

introduction of the original formula. In babies sensitive to cow's milk or soy formulas, a hypoallergenic formula (such as Nutramigen, the base formula in the TRIGR trial) will usually reduce symptoms. Soy formula has not been shown to reduce crying.



Some effective strategies for comforting babies are carrying, swaddling, rocking and other physical soothing techniques. Swings are often used, as are car rides, vacuum cleaners and "white noise" machines. Medicines, such as colic drops or gripe water, do not usually work although simethicone, a gas reducing agent, is sometimes useful. Gripe water is occasionally available with alcohol, but this is unsafe for babies.

The main goal of any treatment is to reassure and support parents who may be stressed, exhausted and just plain nervous. Very often the parents' anxiety keeps the babies crying, and a "time out" can restore some equilibrium, even if only for an hour or two. It is important to realize that colicky babies are by no means unhealthy. They usually keep pace with their peaceful peers.



TRIGR RECRUITMENT CONTINUES THROUGH 2006!

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News Briefs

Nutrition Alert!!!!

Earth's Best Teething Biscuits (both Barley and Wheat) now contain Non-Fat Dry Milk and should not be consumed by TRIGR subjects while in the dietary intervention phase of the study!

A very observant TRIGR mom brought this to our attention. We found that Earth's Best made the recipe change in March, 2005.

Please let your dietitian know if your child has consumed these biscuits and please be sure to check the ingredient label of any new foods given to your child while on the TRIGR intervention.

Is your family growing? Was your first TRIGR child ineligible to continue in the TRIGR Study?

Again, TRIGR enrollment will be open through 2006! If your first TRIGR child was ineligible to continue in the study based on genetic screening results, any future pregnancies will be able to enroll in TRIGR as well.

Unfortunately, if your first child is already eligible to continue in the TRIGR study, subsequent pregnancies are not able to be enrolled.



Would you like share your photos on the TRIGR website?

Send your study coordinator (contact information can be found on page 1) your pictures and they will be posted on the website at www.TRIGR.org. Click on the American flag and then "News and Updates" and you can view other TRIGR children too!

