



TRIGR USA

An NIH-Sponsored Primary Prevention Study for Type 1 Diabetes

TRIGR Tale from St. Louis by Cara Bauer

Kevin and I married in 1993 and we agreed on 3 children. Imagine my surprise when I was diagnosed with type 1 diabetes in September, 1996. My first reaction wasn't "I'm going to die", it was "I'll never have children." I was devastated and depressed. I was referred to an amazing Ob/Gyn and was told with careful management of my diabetes and good prenatal planning, I could have a successful pregnancy. Lily was born April 1, 1998. I can't describe my joyful feelings. I felt I had conquered diabetes because it didn't keep me from having the child I always wanted, a child who is healthy, bright and active. Caroline followed on April 5, 2001. I conquered diabetes again. I was blessed with another healthy, bright and active child.

I discovered TRIGR when Caroline was 6 weeks old. I was disappointed I had not known about the study earlier - I would have happily enrolled Caroline. I promised if I had another child, I would enroll them in the study. Anything I could do to help



Sam Bauer

science figure out the mysteries of diabetes would be worth it. I became pregnant with Samuel in 2003 and enrolled him in TRIGR. I never hesitated a moment. After Samuel's birth on July 11, 2004, he became a study subject. The little guy doesn't know whether to laugh or cry during his blood draw visits, but he does manage to flirt with the TRIGR ladies. He has no idea why he's being poked by strangers. One day I will tell him of the contribution he has given to science, and for his mom. He's happy, bright, healthy and active. He's an amazing addition to my family.

I pray my children never develop diabetes. I know in the big scheme of things, diabetes isn't the end of the world, although it occasionally slows me down. One day, maybe not in my lifetime, but hopefully in the lifetime of my children, a cure will come for diabetes. If Samuel can help find this cure, it would be an answer to my second prayer. My first prayer was answered, three times. I am a lucky woman!

TRIGR Triumphs!

TRIGR is a large multi-center trial investigating both genetic and environmental factors that are related to type 1 diabetes (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 4,600 babies worldwide! In the US alone, we have enrolled over 900

families. Of these families in the US, 710 have given birth and 44 percent of the babies are eligible to continue in TRIGR based on their HLA genotype. Our oldest child is 3½ years old!

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

Spring 2006

Volume 3
Issue 1



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Center Spotlight: Los Angeles

Los Angeles is home to the US TRIGR site #4. The Los Angeles TRIGR team is based at the University of California (UCLA). The team consists of the following dedicated and talented individuals:

Uday Devaskar, MD is a Neonatologist and Professor of Pediatrics at UCLA's School of Medicine. He is currently the Director of the Neonatal Intensive Care Unit (NICU) at UCLA Hospital. Uday is an amazing physician that never forgets his true home—India. Uday travels yearly to India to visit NICUs most in need of equipment, supplies and more importantly teaching of new lifesaving techniques for newborns in distress.

Meena Garg, MD is a Neonatologist and Associate Professor of Pediatrics at UCLA's School of Medicine. Although Meena is not on the forefront of the TRIGR study, she fills the crucial role of being a substitute for Uday when he is out-of-town. Meena is kept busy with several of her own

research projects, such as studying de-novo lipogenesis (or how the body processes and makes different types of fat) in newborns.

Lisa Rogers, PhD RD is the Los An-



The Los Angeles TRIGR Team:

Left to Right: Uday Devaskar, Lisa Rogers, Karin Silk, Cindy Bell (not pictured, Meena Garg)

geles Site TRIGR Study Coordinator and Dietitian. Lisa came to UCLA after an educational tour of the US. She started in her home state of Arizona, moved on to Florida for her dietetic internship and masters degree, and then to California for her doctoral degree and postdoctoral fellowship. Her doctoral degree is in inter-

national nutrition and this is where her passion lies. She has done research in Guatemala and Kenya as well.

Cindy Bell, RNC was TRIGR UCLA's very first Nurse. Cindy came to us from Santa Monica's NICU and helped get the TRIGR study off to a great start at UCLA in early 2002. Cindy left TRIGR in late 2004 for a more permanent position, serving as a NICU Quality Review Analyst for UCLA. She still serves as an important resource for TRIGR UCLA.

Karin Silk, LVN is a licensed vocational nurse and is TRIGR UCLA's new research nurse. Karin is also the mother of two sons—one of which is a 10 year old type 1 diabetic. Karin is half Swedish and half Finnish and very delightful to work with. With Karin's personal background in diabetes and her enthusiasm for research, she makes our team at UCLA complete.

Letter from the Los Angeles Team

Dear TRIGR families,

The US TRIGR site #4 at UCLA is delighted to be part of such an incredible international endeavor to study interventions for the possible prevention or delayed onset of type 1 diabetes. Our site can be found in the heart of the UCLA campus, just inside UCLA's Medical Center and Mattel Children's Hospital. UCLA is located in Westwood, a community in West Los Angeles, that is just 6 miles from the Pacific Ocean in Santa Monica. UCLA's study site is unique for TRIGR in that our staff brings a

background of neonatology and infant nutrition. Although endocrinology is not prominent at our center, this is more than made up for by the number of incredible Pediatric Endocrinologists at our 5 other TRIGR sites in the US.

TRIGR UCLA is extremely proud and thankful for our truly wonderful subjects that come from Arizona, California, Colorado, Hawaii, Nevada, New Mexico and Utah - not to mention the subjects that come from around the world.

TRIGR subjects are a group of very

dedicated and generous individuals with a passion for helping others to understand type 1 diabetes better. They are very much appreciated by all in TRIGR.

Our TRIGR family has grown in a big way over the years, and this should be the last year of recruitment. Please continue to encourage others to be a part of our TRIGR family. Many thanks goes out to each and every one of you.

Have a terrific 2006!



Nutrition Nibbles: Study Formula Options



An important part of TRIGR's nutrition intervention is exposure to the Study Formula (either Enfamil or Nutramigen) in order to help answer the question if what we are feeding our infants during the first 6-8 months of life has any effect on the child later developing type 1 diabetes. There are some ways for an infant to receive Study Formula without having to give the child a bottle of formula. Once the infant starts receiving solid foods, whether it is cereal, vegetables, or fruits, a small amount of Study Formula can be added to a food item every day. For example, when mixing a cereal you can use prepared Study Formula instead of plain water. Study Formula powder can also be added to vegetables or fruits ...you don't need to use much, a teaspoon or

less (just a sprinkle) is fine. If you are making your own baby food there are recipes at the end of the Dietary Advice Booklet which include Study Formula. The newest recipe that we have added is for Teething Biscuits. We have provided this recipe for you to try since many of the commercially prepared Teething Biscuits contain milk or milk products, they cannot be used during the dietary intervention phase of the study. If you are adding Study Formula to your baby's food, please record it on your TRIGR calendar. Note how much Study Formula powder or liquid is being added to the foods and how many times a day. If you have any questions about adding Study Formula to solid foods, please speak with the Dietitian from your TRIGR center

TRIGR Teething Biscuits

- 2 cups wheat or white flour
- 2 Tablespoons milk-free margarine
- $\frac{1}{2}$ cup reconstituted TRIGR study formula

Sift flour and rub in margarine with fingertips until the mixture looks like fine breadcrumbs. Add the reconstituted TRIGR formula and mix to form a soft dough. Turn onto floured board and knead. Roll out dough into long thin rolls and cut into pieces long enough for baby to hold. Place on a lightly greased (milk-free of course) tray and bake in a moderate oven (350° F) for 20 minutes. Turn teething biscuits over and bake until crisp and dried out.

Store in airtight container. May be frozen for later use.

Makes about 20-25 biscuits.

Health News: Your Child's Illness—When to call TRIGR



Another essential part of any research study is collecting data. In all clinical trials, such as TRIGR, it is important to know if your child has had any type of illness. No matter how minor the illness may seem, a sick visit to the doctor or the Emergency Room, or a hospitalization is important for TRIGR to be aware of. Some of these events need to be reported as soon as possible.

Illnesses, accidents or hospitalizations are called "Adverse Events". An adverse event is defined as "an undesirable experience occurring to a study subject during a clinical trial, whether or not it is considered related to the study." In simple terms, we need to know when your child is sick or hospitalized.

When should you call us? You should call as soon as possible for:

- Any hospitalization

- A visit to the doctors office for an illness or accident
- A visit to the Emergency Room for any illness or accident

We will need to know:

- Date the illness began
- Type of treatment
- Where you took your child for treatment
- Medication name and length of time it was given
- Date the illness resolved

Other illnesses that need to be reported, such as colds, flu, vomiting, diarrhea, fevers, etc should be noted on your child's TRIGR calendar. We will obtain that information from you at our next call or visit.

Along with any illness or hospitalization, we would like to know if your

baby is having any problems with the study formula. If it is suspected that the baby has "formula intolerance", we will conduct a "Study Formula Challenge Test". We will ask you not to give the study formula for at least 2 weeks. We will supply the Nutramigen that will be needed during the elimination period. You will be asked to keep a record of the baby's symptoms during this two week period. After two weeks, we will ask you to reintroduce the study formula to the baby in small amounts until the baby is able to tolerate the study formula.

The information that is obtained regarding your child's illness is reported to the Data and Safety Monitoring Board. This committee plays an essential role in protecting the safety of study participants and assuring the integrity of the study.



TRIGR RECRUITMENT CONTINUES THROUGH 2006!

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News Briefs

Congratulations!

Congratulations goes out to TRIGR mom, Jackie Kravitz, for chairing and raising \$100,000 for the American Diabetes Association's first-ever "Walk for the Cure" in Yuma, Arizona.

Jackie is a wife and working mother of two wonderful children. Jackie is also a type 1 diabetic. She and her family are very committed to helping find a prevention & cure for type 1 diabetes. She has made incredible efforts to raise funds for the ADA and is also participating in TRIGR with her son, Cooper.



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!



The Axelrod girls, Hawaii