



TRIGR Newsletter

TRIGR in Germany



TRIGR team Berlin



TRIGR team Hannover

In the context of the international TRIGR study with 15 participating countries Germany is involved with centers in Berlin and Hannover and we aim at recruiting 80 families per year in the study. Although there are about 190000 patients with type 1 diabetes in Germany, we were confronted by a considerable challenge "How could we reach out to the relevant families nationwide?"

We tried to identify the first families with posters, flyers, information brochures and with our own German website (www.trigr.de). Other activities included articles in about 20 nationwide magazines, not only diabetes specific ones, announcements on diabetes specific websites, information activities such as information booths at fairs and meetings and finally a newsletter to former patients, diabetologists, gynecologists, geneticists and midwives. Over the following 33 months we received sometimes more and sometimes less telephone calls and mails, the number of which varied from time to time. Altogether we had about 300 contacts. We were all the time excited, whether we would be able to reach 80 families per year or not? We have been happy to see that we have come very close to our target. We have just now received the signed consent of the family number 215 and we have so far been able to include 82 newborns infants with increased risk of diabetes into the study.

Every family does not live close to the study centre and can cope with distance to the study centre. Therefore we have organized study visits by contacting local hospitals and doctors. We have invested a lot of time in these arrangements by contacting the families and the centers with endless telephone calls, letters and mails. In addition we ship the necessary materials for blood sampling and the study formula to the families. To put these activities into numbers: 300 contacts to make arrangements for 300 interested families to register and sending out 300 information brochures. About 200 delivery rooms had to be contacted for 215 deliveries nationwide. For the 82 eligible newborns we have by now prepared and sent out 324 times packages

containing tubes, questionnaires, and information sheets and correspondences to be used within the first year of life of the participating child. These activities have involved many logistic problems. For example, the materials did not arrive on time, the courier did not pick up the blood tubes or a tube was broken. Nevertheless most of the problems have been solved on time. Accordingly we are confident that we will be able to keep up our activities and continue to do a good job.

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In the following Timo, born on 19 Oct 2002 as the 13th TRIGR – child in Germany, would like to report about his study participation. My mum was pregnant in 2002 for the second time. She read an article about the TRIGR study in a magazine and she was interested in participating.

My mother thought, that the more subjects take part in studies the more is learned about things that will be advantageous for patients with type 1 diabetes. Maybe it will become possible even to prevent the development of diabetes. After a pleasant and informative talk with Mrs. Aschemeier it was clear to my parents that they would like to participate in the study. Initially my father was a little skeptic. He had worries that the frequent blood sampling would not please me. But my mother argued with him that the blood draws are not so bad and that we babies forget them quickly. Some days earlier than planned I was welcomed by the world. During the next 9 months my mother and Mrs. Aschemeier had frequent telephone calls. I believe it was important to know for the study follow-up, what kind of food I received, and whether and how often I was sick. In addition my mother had to make notes at home, when I started with the study formula and how much I had of it. Because I enjoyed breast milk I started with the study formula for the first time at the age of 6 months.

At the age of 3 months I introduced myself personally to Mrs. Aschemeier and her colleagues in the study centre for the first blood sampling. The subsequent blood samples were to be drawn by my pediatrician in my home town. Although I do not like the prick, I have decided to reduce my protests. Fortunately the blood glucose and HbA1c values have been okay. After all, I am sure that this study will benefit future generations and I am proud to be the 13th German TRIGR – baby.

Thomas Danne, Bärbel Aschemeier and Timo



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TRIGR in Bilbao



We wish to report about our TRIGR experiences in Bilbao, although we do not have any special recipe. We have taken two strategies to inform about the TRIGR trial in Bilbao (Basque country and Navarra), Spain, the first one targeting doctors and the other families.

First, in our area, we have a very good relationship with adult and pediatric endocrinologists. In addition, we have a very well organized system with antenatal clinics and midwives who have been cooperating very actively when identifying pregnant women with type 1 diabetes and/or affected husbands.

Our direct approach to the families has been organized through our local diabetes association. In our region, the diabetes association publishes journals with general diabetes information and we have arranged for TRIGR advertisements to be included.

In addition, our TRIGR team in Bilbao is highly motivated to work with the families. Firstly, the families can contact us 365 days a year and 24 hours a day, we have been working hard in arranging any time for contacts feasible for the families in order to explain the general aim of TRIGR as well as all the details about the trial. We have made families to feel that we are close to them. We are in a way "members" of their families because we establish a strong relationship with the families and the trial participants. They can feel our commitment from the very beginning, and we have a special interest in that they feel comfortable. Many people, especially diabetic patients, are sometimes reserved, and they may have the impression that they are only "experimental animals" for scientists. In such circumstances, we have to be extremely sensitive and sympathetic with them. We have to have enough time to discuss with them possible negative consequences of taking part in the trial and how they feel and think about the study. Of course a few families have refused to participate in TRIGR, but most of them are families who have not received all the information in time.

We adapt the TRIGR visit schedules to the family's timetables. We are very lucky in having pediatric nurses and a pediatrician strongly engaged in diabetes education and helping TRIGR families in other issues apart of TRIGR visits and interviews.

It has taken us some time in making our diabetic population prone to the idea of taking part in an international trial. This has been especially challenging for us because Spanish people are not very used to participate in scientific studies, and even more when thinking of their babies as becoming "study subjects" in the TRIGR trial.

To summarize, we have established a strong network in our area (Basque country and Navarra) with pediatricians, endocrinologists and midwives in order to identify as many relevant families as possible for TRIGR, and we have tried to be familiar and easily "reachable" for the families.

Then, if you combine time with communication and empathy you get our success formula.

Now our challenge is to keep the participating families in the study for the 10 year follow-up.

Luis Castano (Area Coordinator), Teba Gonzalez (Dietician coordinator) on behalf of Bilbao TRIGR Team.

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Awards



Last year Germany and Czech Republic were rewarded for excellent recruitment and compliance. This year Principal Investigator rewarded Australia and Bilbao (Spain) in Toledo April 2, 2005. The competition between the countries was extremely even.

Editor Matti Koski



TRIGR Newsletter

TRIGR babies' food habits



Data from TRIGR dietary interviews conducted so far show that Finnish TRIGR babies start to receive potato and vegetable purées at about 3.5 months of age and fruit and vegetable purées at about 4 months of age. Finnish babies are given complementary foods at a relatively young age, before it is recommended. The Finnish dietary guidelines for young children recommend that infants are exclusively breastfed until the age of 6 months and that complementary foods are introduced thereafter. It is, however, emphasised that the timing of complementary feeding is always based on individual needs, and solid foods can be started earlier, if needed.

At 6 months of age, already 95% of Finnish TRIGR children received potato and vegetable purées as well as fruit and berry purées. Wheat, oat, barley or rye was used by 76% of the 6-month-old infants, and other cereals such as corn and rice was used by 66% of the infants at the same age. The infants were given the first tastes of meat shortly after starting cereal foods. However, fish was started later than meat. At six months of age, fish was used by 35% of the infants and at 8 months of age, it was used by 55% of the subjects. Egg consumption was rare; it was used by only 4% of the 6-month-old babies and by 24% of the 8 month-old-infants.

TRIGR data from all over the world show that there are cultural differences in babies' food habits. In European countries, potato and vegetable purées are the first foods given to babies, while in the United States and Canada the first tastes are usually infant cereals. The TRIGR babies in North America started to receive meat later than in Europe. In Finland, many 6-month-olds already received meat at a daily basis. At 7 months of age, 59% of the Finnish TRIGR children used meat daily, and at 8 months of age, the proportion was 75%. On the other hand in Canada,

for example, the proportions were 13% and 29%, respectively. More information on the children's food habits is obtained, as the TRIGR study goes on and more children participate.

Liisa Vähätalo, Nutrition coordinator

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Questions and answers

What are the most common symptoms and signs of type 1 diabetes in childhood at the time of diagnosis?

When a majority of the insulin-producing beta cells are destroyed, the body is no longer able to regulate blood sugar levels and the child develops some or all of the classic symptoms of diabetes:

Excessive thirst, urination, hunger, secondary enuresis (in which previous bedtime control is lost), weight loss, fatigue, vomiting, and abdominal pain. On testing the child has a high blood glucose concentration and glucose and ketones in the urine.

When will the family be informed about the specific HLA risk genotype, the autoantibody levels and which type of study formula the child has been on?

The specific HLA genotype will be told when the study has been completed. The family will receive the data on the autoantibody levels up to the age of 6 years within 6 months after the 6-year visit.

Information on the type of study formula will be provided after the study has been completed.

Does breast feeding prevent type 1 diabetes?

Breast milk is clearly the best feeding for the baby, it protects from many infectious diseases like diarrhea. However, we do not know whether it prevents type 1 diabetes. Most of the studies available at the moment suggest that breast feeding may not be related to the development of type 1 diabetes.

Mikael Knip and Suvi Virtanen



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TRIGR statistics

Our target in the TRIGR trial is to screen altogether 4516 children and our estimation is that 2032 randomized children should continue in the study after genetic HLA screening. By the end of March 2005 we are over half way through and the study is progressing well. So far 3438 mothers have been registered and 2982 children randomized. Out of the randomized children 1278 continued in the study after the genetic screening. Somewhat more subjects were HLA ineligible and for several children we are still waiting for the HLA results.

Region	Registered Mothers	Randomized Children				
		Total	*Ineligible Children	HLA Results Not Available	HLA Ineligible	HLA Eligible
North America	1586	1352	44	59	673	576
Europe	1852	1630	18	48	862	702
	3438	2982	62	107	1535	1278

*Child does not fulfil participation criteria

Families in the study

The family history of the children who are continuing in the study at the end of March 2005 is presented in the table below. We have more families participating where the mother is affected by type 1 diabetes than families where the father is affected. Families with the mother affected are 612 and families with the father affected are 430. At the moment 179 families are participating where a sibling of the subject is affected by type 1 diabetes. In 57 families more than one family member has type 1 diabetes.

Region	Family Member With Type 1 Diabetes				
	Mother	Father	Sibling	More Than 1 Family Member	Total
North America	290	168	92	26	576
Europe and Australia	322	262	87	31	702
<i>Total</i>	<i>612</i>	<i>430</i>	<i>179</i>	<i>57</i>	<i>1278</i>