Greetings from Principal Investigator of the TRIGR project

I would like to greet all families involved in our TRIGR project (Trial to Reduce the Incidence of IDDM in Subjects Genetically at Risk). We highly appreciate your interest to join the project. In fact, your participation is crucial to the success of the study. We have well-trained and highly motivated TRIGR study teams in 14 countries on three continents. However, without the parents’ contribution the teams could not succeed. The randomization for the study was started in the first countries in May 2002. In late March 2004 we had over 2,000 registered mothers, and 715 newborn infants have proved to be HLA-eligible. We look forward to have the recruitment completed in the year 2006. Another important issue besides recruitment is compliance. We follow this carefully with the help of our Data Management Unit (DMU), and also here your efforts are important, in helping us to collect accurate information on the study subjects during the follow-up.

My sincere thanks to all of you, and best wishes for a continuous good collaboration!

Families in the study

The family information of the children, that are continuing in the study between the two regions North America and Europe & Australia looks as follows:

<table>
<thead>
<tr>
<th>Family members with type 1 Diabetes</th>
<th>Mother</th>
<th>Father</th>
<th>Mother &amp; Father</th>
<th>Mother &amp; Sibling</th>
<th>Father &amp; Sibling</th>
<th>Mother &amp; Father &amp; Sibling</th>
<th>Sibling only</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>159</td>
<td>94</td>
<td>6</td>
<td>4</td>
<td>6</td>
<td>0</td>
<td>50</td>
<td>319</td>
</tr>
<tr>
<td>Europe &amp; Australia</td>
<td>142</td>
<td>149</td>
<td>8</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>38</td>
<td>346</td>
</tr>
<tr>
<td></td>
<td>301</td>
<td>243</td>
<td>14</td>
<td>5</td>
<td>13</td>
<td>1</td>
<td>88</td>
<td>665</td>
</tr>
</tbody>
</table>
Hugo is now one year old, how is he? Thank you very much, everything is fine. Hugo has had a little flu, but nothing serious.

How did you get the information about the TRIGR Study? I was informed at the control visit in the antenatal clinics at hospital.

Do you think that it was difficult to decide to join the study? No, it was easy. I made up my mind right away and after discussions with my husband we decided to take part in the study.

How did you feel after hearing the positive HLA result? Were you disappointed or worried? All information was given quite well and I was not too worried because Hugo’s chance to get diabetes is low in spite of having the susceptibility to diabetes.

Is it heavy to take part in the study? Not at all, I think that it has been interesting. If Hugo had been our first child it might have been heavy. With the first child you have to learn so many new things.

Are there too many/few contacts from the study center (interviews, follow-up visits)? I am quite systematic by nature so this kind of project is working fine with me.

How would you describe the cooperation with the TRIGR staff? The cooperation has been good; we have not had any problems.

Did you receive enough information on TRIGR, on dietary restrictions during the intervention and on the duration of the intervention? We got all information needed and there is always a possibility to get more information at the follow-up visits.

Was it difficult or complicated to use the study formula powder? Yes, at the beginning of the intervention I felt the use of the powder a bit complicated, but after got used to it, I have had no problems. The powder could dissolve better with water.

Did you have any difficulties with transition from the intervention diet to the usual diet? After the dietary intervention I gave Hugo standard formula and he drank it with good appetite right away.

What would you like to say to families who are interested in attending the study, but have not decided yet whether to participate or not? I think this is an important study and I can recommend participating TRIGR. Personally I feel that we have received more than given. I appreciate regular visits at doctor.

Tasting the study formula

The infant formula used in the TRIGR study is balanced and contains all the nutrients that a baby needs. The nutrient content of the Study Formula is comparable to the nutrient content of other commonly used infant formulas on the market. Introducing new foods into a baby’s diet, whether it is infant formula or other food, demands the baby to become familiar with new flavours. It may take days or even weeks for the baby to get used to a new food and this process requires patience from the parents. But at the end babies usually start to like most of the new foods.

The unfamiliar taste and smell of the Study Formula results from splitting the proteins into smaller parts. A baby perceives new flavours and smells in a different way than an adult. The ability to accept unfamiliar flavours develops by age and especially by getting frequently exposed to it. In general, the TRIGR babies have accepted the Study Formula very well.