The Global Platform for the
Prevention of Autoimmune Diabetes

GPPAD SCIENCE-NEWSLETTER

Issue 03/ May 2022

DEAR READER,

Welcome to the third GPPAD Science-Newsletter. In our newsletters, we keep you up to date on the most important developments of our GPPAD projects. If you do not yet know who we are and what we do, then please read our previous newsletters. You can find these at this link.

We would like to share two highlights from our GPPAD project with you: Newcastle (United Kingdom) has just joined GPPAD as a new study site. Furthermore, more than 300 babies were already enrolled in our new prevention study SINT1A (**S**upplementation with B. **IN**fantis for Mitigation of **T**ype **1** Diabetes **A**utoimmunity). Read more about SINT1A in our newsletter below.

Feel free to forward the newsletter to others who may be interested. If you have not yet subscribed to the newsletter, please register here.

I hope you enjoy reading the GPPAD Science Newsletter and look forward to having you join us on our journey to a world without type 1 diabetes.

With best regards,

Prof Dr Anette-Gabriele Ziegler
(Director, Institute of Diabetes Research, Helmholtz Munich)

SINT1A STUDY

Primary prevention study

The SINT1A study is a research study for infants with an increased risk of type 1 diabetes. The aim of the study is to prevent the development of islet autoimmunity and type 1 diabetes. Infants up to the age of six weeks can participate.

More information:

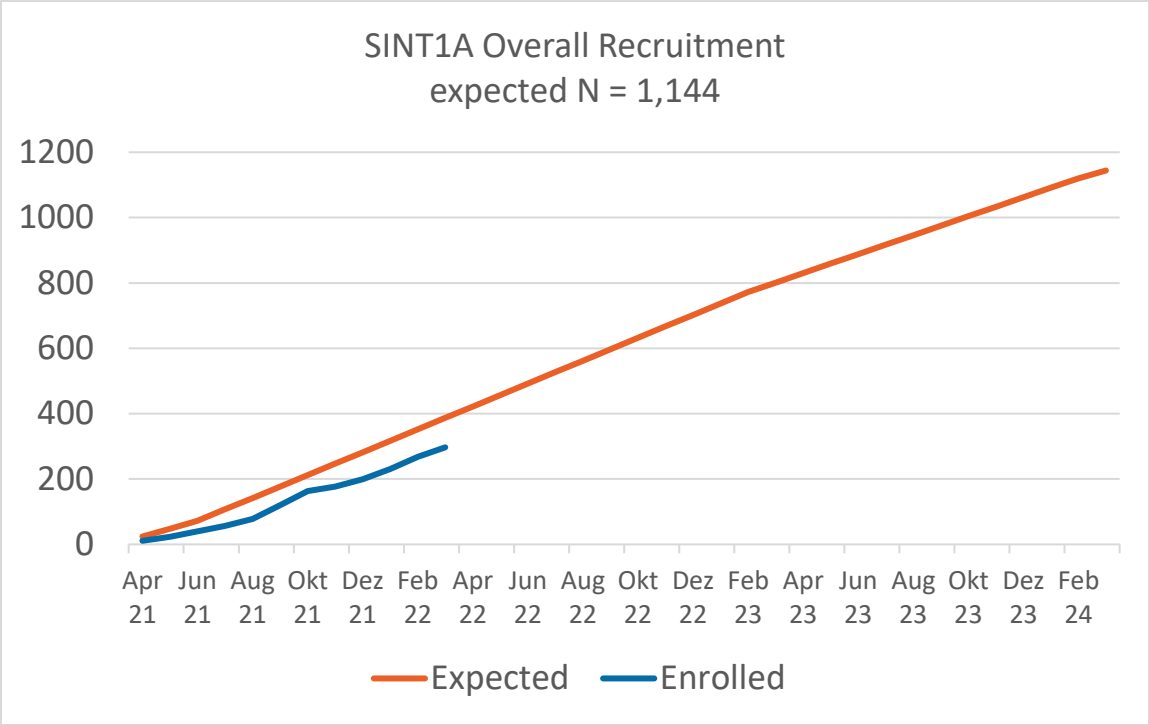
- **Design:** randomised, placebo-controlled, double blind, multicentre, multinational, primary prevention trial
- **Randomization:** 1:1 (B. *infantis* EVC001 or placebo)
- **Inclusion age:** 1-6 weeks
- **Intervention**: B. infantis EVC001
- **Treatment duration:** until 12 months of age
- **Follow-up:** 2.5-5.5 years after intervention
- **First participant enrolled:** 22-Apr-2021
- **Trial duration:** until 2027
- **Target:** 1,144 participants
- **Primary outcome:** development of persistent confirmed multiple beta-cell autoantibodies
- **Secondary outcome:** type 1 diabetes, celiac autoimmunty
- **Exploratory outcome:** allergy

For more information, please refer to the study protocol publication and the overview on clinicaltrial.gov or read our second newsletter.

Current status

- A total of 338 children were enrolled in the SINT1A study at a median age of 37.8 days (range 19 - 55 days).

- At the moment 315 children are in the intervention, 23 in the follow-up phase.



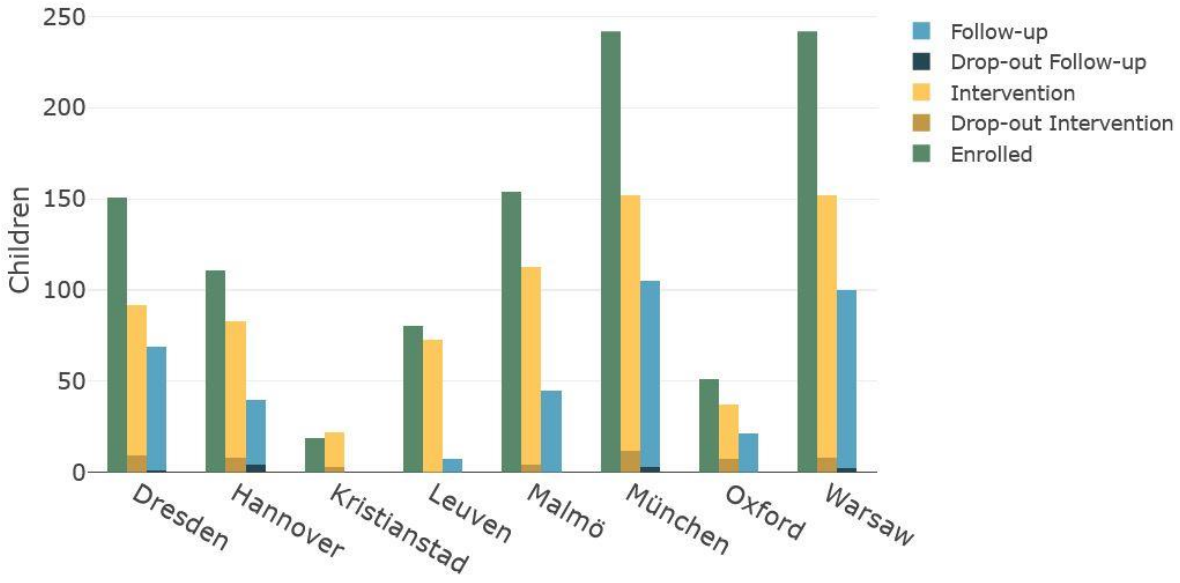
POINT

Recruitment completed

A total of 1,050 children were enrolled in the POInT study (**P**rimary prevent**IOn** **T**rial) at a median age of 6.1 months (range 3.9 - 7 months). Enrollment for this study is complete. At the moment 691 children are in the intervention, 359 in the follow-up phase.

- **First participant enrolled:** 07-Feb-2018
- **Last participant enrolled:** 24-Mar-2021
- **Enrollment period planned:** 3.5 years, Actual ~3.2 years
- **Projected study end:** Jan-2025

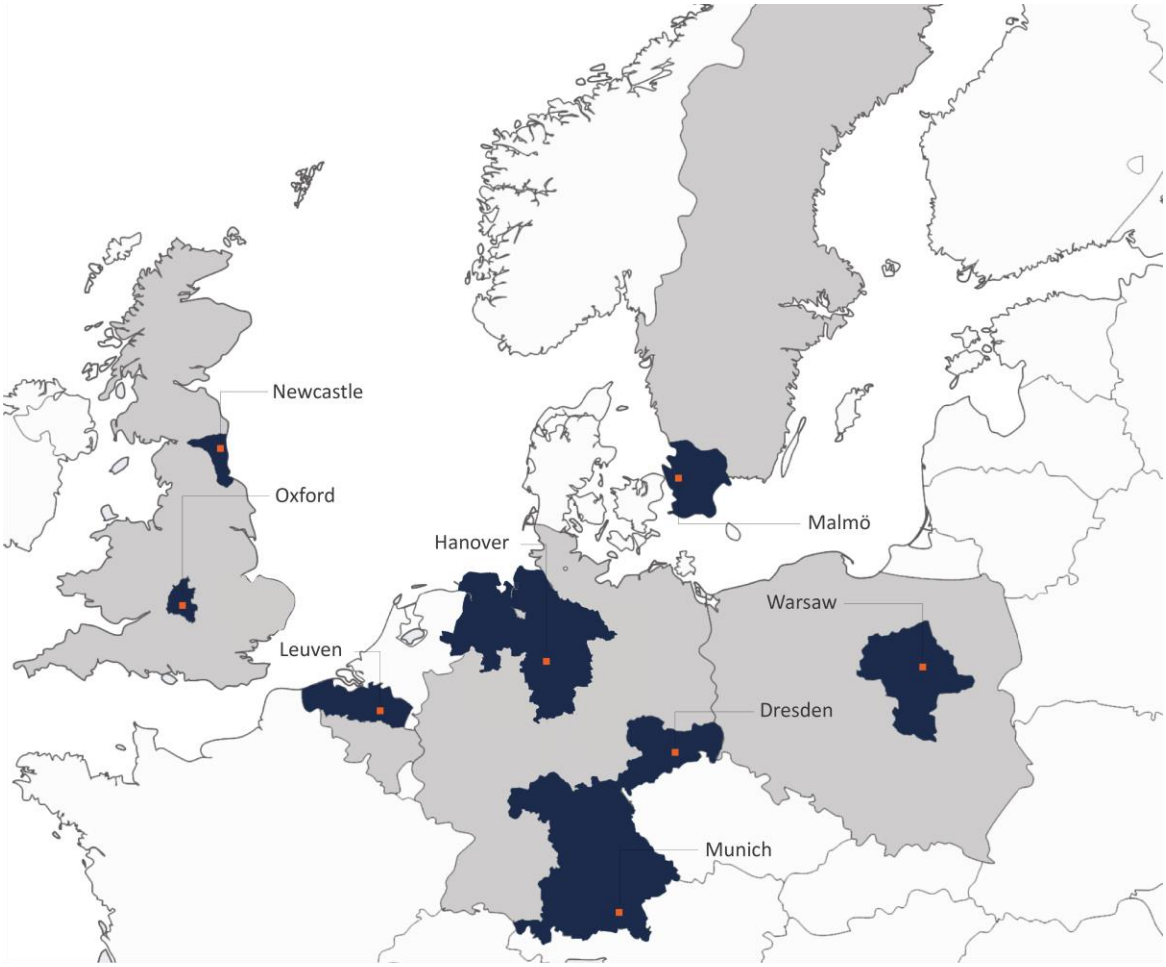
Participants take the Investigational Medicinal Product IMP (oral insulin or Placebo) daily with food until their 3rd birthday, and are followed 6-54 months after intervention. The numbers of enrolled children and their actual status (intervention, follow-up or drop-out) at the different participating GPPAD study center are shown here:



For more information, please refer to the study protocol publication and the overview on clinicaltrial.gov or read our first newsletter.

PARTICIPATING SITES

All study institutions in Europe



GPPAD BIOBANK AND DATA SHARING

Application to access GPPAD data & biobank sample

GPPAD has established a data- and biobank repository. The GPPAD biobank contains extensive sample material (Serum, Plasma, RNA, PBMC) of the study participants.

- For application to access GPPAD data, please click **here**
- For application to access the GPPAD biobank, please click **here**