

The Global Platform for the Prevention of Autoimmune Diabetes

GPPAD SCIENCE-NEWSLETTER

Issue 01/2021

DEAR READER,

Welcome to the very first issue of our GPPAD Science-Newsletter. From now on, we will keep you updated on the most important developments of GPPAD projects and research.

If you are interested in receiving this newsletter in the future, please register HERE

GPPAD is committed to <u>data and bio-sample sharing</u>, which may also be interesting for your research.

Please send any questions or feedback to cc@gppad.org. Of course, we are excited to share our journey towards a world without type 1 diabetes with you!

Enjoy reading! Your GPPAD team

WE RESEARCH. WE DEVELOP. WE FIGHT.

FOR A WORLD WITHOUT TYPE 1 DIABETES.

GPPAD - WHO WE ARE, WHAT WE DO

The Global Platform for the Prevention of Autoimmune Diabetes (GPPAD) is a research organization that unites academic institutions and hospitals in five European countries under the lead of Helmholtz Zentrum München. We ...

- provide an international infrastructure to enable type 1 diabetes (T1D)
 primary prevention trials
- identify infants with an elevated genetic risk of developing T1D
- offer participation in randomized controlled trials aiming to reduce the incidence of islet autoimmunity and T1D in children

GPPAD STUDIES

Screening study for the risk of developing T1D

GPPAD conducts screening for genetic predisposition of T1D in infancy using a polygenic SNP risk score: The study is known as Freder1k (Germany, Belgium, Poland), Ingr1d (UK) and Astr1d (Sweden), respectively.

- GPPAD screening for high genetic risk of developing T1D is active in five
 countries in Europe (Belgium, Germany, Poland, Sweden, UK). The GPPAD
 investigators and collaborators have established a screening network in their
 respective regions with local affiliate partners such as obstetric clinics,
 neonatologists, primary care pediatricians, and newborn screening
 laboratories to perform the actual screening for T1D risk.
- Genetic risk is determined using a combination of family history and up to 51 SNPs. DNA extraction from filter paper blood spots and genetic typing are done at LGC, UK.
- High genetic risk is defined as having a risk above 10 % (25 fold higher than the general population) of developing multiple beta cell autoantibodies (stage 1 T1D) by 6 years of age.

A total of 1.15 % of screened infants were identified to have a high genetic risk. By TODAY **243,499** children have been screened with a monthly rate of **8,000** throughout the last 12 months:

Belgium (Flanders): 12,783

Germany (Bavaria, Lower Saxony, Saxony, Thuringia): 130,669

Sweden (Skane): 12,662 Poland (Warsaw): 74,442

UK: 15,403

POINT: Primary Oral Insulin Trial



Children with high genetic risk for T1D and their parents or guardians are asked to participate in the oral immunotherapy study POInT.

The POInT study aims to train the immune system, induce immune tolerance through daily sensitization with insulin powder, and thereby reduce the incidence of betacell autoantibodies and diabetes in childhood.

Sponsor: Faculty of Medicine, Technical University Munich,

Germany

Design: CT-IMP, phase IIb, randomized controlled trial

Randomization: 1:1 (oral inuslin or placebo)

Inclusion age: 4-7 months

Treatment duration: until 3 years of age

Follow-up: up to 7 years of age or until the end of the trial

Trial duration: until 2025

Target: 1040 participants

Insulin dose: 7.5 mg (2 months), 22.5 mg (2 months), 67.5 mg (until

end of intervention) or placebo

Primary outcome: T1D (multiple beta cell autoantibodies or diabetes)

For more information, please refer to the <u>study protocol publication</u> and the overview on <u>clinicaltrial.gov</u>.

Currently enrolled participants: 964

Participants with currently completed intervention phase: 52

GPPAD BIOBANK AND DATA SHARING



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

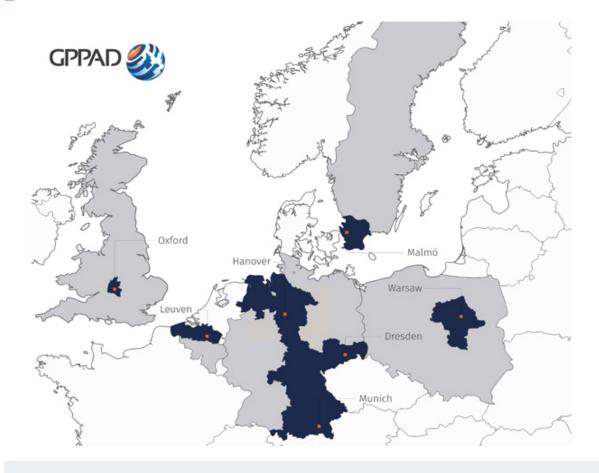
For application to access the GPPAD Biobank, please click here

PUBLICATIONS

Winkler C, Haupt F, et al. Identification of infants with increased type 1 diabetes genetic risk for enrollment into Primary Prevention Trials-GPPAD-02 study design and first results. Pediatric Diabetes 2019;9 20(6):720-727. doi: 10.1111/pedi.12870

Ziegler AG, Achenbach P, Berner R et al. Oral insulin therapy for primary prevention of type 1 diabetes in infants with high genetic risk: the GPPADPOINT (global platform for the prevention of autoimmune diabetes primary oral insulin trial) study protocol. BMJ Open 2019;9 9:e028578. doi:10.1136/bmjopen-2018-028578

PARTICIPATING INSTITUTIONS



Dresden (Saxony & Thuringia): Prof Dr Ezio Bonifacio & Prof Dr Reinhard Berner

Leuven (Flanders): Prof Dr Kristina Casteels

Munich (Bavaria): Prof Dr Anette-Gabriele

Ziegler & Dr Christiane Winkler

Warsaw: Prof Dr Agnieszka Szypowska & Dr

Mariusz Ołtarzewski

Hanover (Lower Saxony): Prof Dr Olga Kordonouri & Prof Dr Thomas Danne

Malmö (Skane): Prof Dr Helena Elding Larsson &

Prof Dr Markus Lundgren

Oxford: Prof Dr Matthew Snape & Dr Manu Vatish

The GPPAD Coordinating Centre is located at the Institute of Diabetes Research, Helmholtz Zentrum München:

Director: Prof Dr Anette-Gabriele Ziegler **Deputy Director:** Prof Dr Peter Achenbach

External Expert in Study Statistics: Prof Jörg Hasford

Data Management: Dr Florian Haupt

Ethical and Regulatory Affairs: Stefanie Arnolds **Central Office Coordination:** Dr Melanie Gündert



If you no longer want to receive the newsletter, please unsibscribe here. If this email is not displyed correctly, please click here.

GPPAD - Institute of Diabetes Research, Helmholtz Zentrum München

Ingolstädter Landstraße 1 85764 Neuherberg Deutschland

cc@gnnad.org