ISRCTN50665418 https://doi.org/10.1186/ISRCTN50665418

Randomised, double-blind, placebo-controlled, multi-centre, parallel group study to investigate the safety and tolerability as well as the immunological and clinical effects of multiple subcutaneous doses of DiaPep277 in latent autoimmune diabetes in adults (LADA) patients

Submission date
12/09/2005

Registration date
21/10/2005

Last Edited
07/09/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

601/PO

Study information

Scientific Title

Study objectives
Investigate the safety and tolerability and the immunological and clinical effects of multiple doses of DiaPep277.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Latent autoimmune diabetes in adults.

Interventions
Treatment with subcutaneous injections of DiaPep277 or placebo in three different treatment groups with different schedules for a period of approximately 18-20 months. Follow up until 2 years after the first administration of study drug.

Group A: Administration of 1 mg DiaPep277 or placebo at the start of the study and 1 month, 6 months, 12 months and 18 months later. In total five administrations.
Group B: Administration of 1 mg DiaPep277 or placebo at the start of the study and 2 weeks, 4 weeks, 6 weeks and 8 weeks later. Further administrations in intervals of approximately 3 months. In total 10 administrations.
Group C: Administration of 0.2 mg DiaPep277 or placebo at the start of the study and 2 weeks, 4 weeks, 6 weeks and 8 weeks later. This course is repeated 6 months, 12 months and 18 months after the first administration. In total 20 administrations.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

DiaPep277

Primary outcome(s)
Pancreatic beta-cell function, insulin independency or change in insulin dose, metabolic control: most parameters at every 6 months.

Key secondary outcome(s))
Immune response (every 6 months), clinical safety and tolerability at each visit.

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of diabetes mellitus according to World Health Organisation (WHO) classification for more than 2 months and less than 5 years before enrolment
2. Diabetes controlled by diet, oral antidiabetics or insulin therapy
3. Positive for glutamic acid decarboxylase (GAD) autoantibodies
4. Male caucasian patients, aged 30 to 50 years, or female caucasian patients, aged 30 to 50 years, who are not pregnant and use safe contraceptive methods

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with secondary diabetes mellitus
2. Any previous insulin treatment before the first injection of study drug
3. History of intolerance or contraindications to oral hypoglycaemic medications
4. Clinical evidence of any severe diabetes-related complication
5. Allergy to investigational drug
6. History of severe allergy or asthma
7. Known immune deficiency from any disease, or a condition associated with an immune deficiency
8. Use of immunosuppressive or immunomodulating agents or cytotoxic therapy, or any medication which, in the opinion of the investigator, might interfere with the study

Date of first enrolment
17/04/2001

Date of final enrolment

31/12/2005

Locations

Countries of recruitment
United Kingdom

England

Germany

Study participating centre
University of London
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
DeveloGen AutoImmune GmbH (Germany)

ROR
https://ror.org/03d3v3e93

Funder(s)

Funder type
Industry

Funder Name
DeveloGen AutoImmune GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration