

# 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

|                                        |                                                                |                                                      |
|----------------------------------------|----------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>12/09/2005   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>21/10/2005 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>07/09/2007       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                                | <input type="checkbox"/> Results                     |
|                                        |                                                                | <input type="checkbox"/> Individual participant data |
|                                        |                                                                | <input type="checkbox"/> 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**

## 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

### Primary study design

Interventional

### Study design

Randomised controlled trial

### 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

