

# A phase III, multinational, randomised, double-blind, placebo-controlled, parallel-group study to investigate the clinical efficacy and safety of Diapep277™ in newly diagnosed type one diabetes patients

**Submission date**

28/09/2005

**Recruitment status**

No longer recruiting

**Registration date**

21/10/2005

**Overall study status**

Completed

**Last Edited**

13/06/2016

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Paolo Pozzilli

**Contact details**

Universita' Campus Bio-Medico  
Piano Facolta' di Medicina  
via Emilio Longoni, 83  
Rome  
Italy  
00155

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00615264

## Secondary identifying numbers

901

# Study information

## Scientific Title

A phase III, multinational, randomised, double-blind, placebo-controlled, parallel-group study to investigate the clinical efficacy and safety of DiaPep277™ in newly diagnosed type one diabetes patients

## Acronym

DIA-AID

## Study objectives

To test the hypothesis that pancreatic beta-cell function with DiaPep277™ is superior to that with placebo after 24 months.

## 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Type one diabetes

## Interventions

1 mg DiaPep277™ or placebo will be administered subcutaneously at baseline (zero), one, three, six, nine, 12, 15, 18 and 21 months visits for a total of nine administrations.

Both treatment groups will be balanced for HbA1c values (HbA1c inferior to 7.0% and HbA1c superior or equal to 7.0%) and basal fasting C-peptide concentrations (C-peptide < 0.40 nmol/L and C-peptide ≥ 0.40 nmol/L). [Changed on 05/03/07 from ' Both treatment groups will be balanced for HbA1c values (stratum A: patients with HbA1c less than 7.0%, stratum B: patients with HbA1c equal to or more than 7.0%).'].]

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Diapep277™

## **Primary outcome measure**

Investigate the effect of DiaPep277™ versus placebo in patients with Type one Diabetes Mellitus on pancreatic beta-cell function as measured by stimulated C-peptide secretion after 24 months

## **Secondary outcome measures**

1. Assess the effect of DiaPep277™ on insulin dose requirement after 24 months
2. Assess the effect of DiaPep277™ versus placebo on metabolic control as measured by % HbA1c after 24 months and by glucose profile during the study
3. Assess the safety and tolerability of DiaPep277™ during the study
4. Assess the effects of DiaPep277™ on the occurrence of hypo- and hyper-glycemic events during the study

## **Overall study start date**

01/10/2005

## **Completion date**

31/08/2010

# **Eligibility**

## **Key inclusion criteria**

At screening:

1. The patient has a diagnosis of type one diabetes mellitus according to the American Diabetes Association (ADA)/World Health Organisation (WHO) for up to 3 months (changed from 6 months on 05/03/2007)
2. Evidence of residual beta-cell function demonstrated by basal fasting C-peptide concentrations more than or equal to 0.22 nmol/l
3. Presence of one or more of the following criteria:
  - 3.1. At least one diabetes-related autoantibody: IA-2, insulin or glutamic acid decarboxylase (GAD) at screening and/or
  - 3.2. Age at diagnosis less than 20 years and ketonuria at diagnosis
4. The patient is on insulin treatment for diabetes since diagnosis
5. The patient is male or female, aged 16 to 45 years, inclusive
6. If a female of child-bearing potential, the patient is not pregnant or lactating, and will use oral

hormonal contraception or other equally effective contraceptive methods throughout the study. The partners of male patients, who are of child-bearing potential, should also use adequate contraception in order to avoid pregnancies

Inclusion criteria removed on 05/03/2007: the patient has HbA1c of less than or equal to 9% within seven days prior to baseline visit

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

400

**Key exclusion criteria**

1. The patient is treated with inhaled insulin (changed from 'has an insulin pump in situ or is treated with inhaled insulin' on 05/03/07)
2. The patient has clinical evidence of any diabetes-related complication that in the opinion of the Investigator would interfere with the patient's participation in and/or completion of the study
3. Patient has history of endogenous allergic reactivity
4. The patient has a known immune deficiency from any disease, or a condition associated with an immune deficiency
5. The patient is receiving immunosuppressive or immunomodulating agents or cytotoxic therapy, or any medication that, in the opinion of the Investigator, might interfere with the study
6. Patients with severe renal failure at the screening visit (as defined by glomerular filtration rate less than 30 ml/min/1.73 m<sup>2</sup> by Cockcroft and Gault calculation), hyperlipidemia is allowed
7. The patient has liver disease such as cirrhosis or chronic active hepatitis

Exclusion criteria removed on 05/03/2007: severe ketonuria (+++ on urine stix testing; ++ on repeated urine stix testing)

**Date of first enrolment**

01/10/2005

**Date of final enrolment**

31/08/2010

**Locations****Countries of recruitment**

Austria

Czech Republic

Finland

France

Germany

Greece

Israel

Italy

South Africa

Spain

United Kingdom

**Study participating centre**  
**Universita' Campus Bio-Medico**  
Rome  
Italy  
00155

## **Sponsor information**

**Organisation**  
Andromeda Biotech Ltd (Israel)

**Sponsor details**  
PO Box 4145  
Ness Ziona  
Israel  
74140

**Sponsor type**  
Industry

**ROR**  
<https://ror.org/00kyj9h67>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**

Andromeda Biotech Ltd (Israel)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a>   |         |              |            | No             | No              |
| <a href="#">Results article</a> | results | 01/07/2014   |            | Yes            | No              |
| <a href="#">Results article</a> | results | 01/07/2014   |            | Yes            | No              |