ISRCTN55429664 https://doi.org/10.1186/ISRCTN55429664

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	Recruitment status
28/09/2005	No longer recruiting
Registration date	**Overall study status**
21/10/2005	Completed
Last Edited	**Condition category**
13/06/2016	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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^2 by Cockroft 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?
Basic results				No	No
Results article	results	01/07/2014		Yes	No
Results article	results	01/07/2014		Yes	No