

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy and Safety Comparison of Two Different Biphasic Insulin Aspart 30 Treatment Initiation Regimens Followed by intensification in Subjects with Type 2 Diabetes Mellitus Not Achieving Glycaemic Targets on Oral Anti Diabetic Drugs alone in Iran

Protocol summary

Summary

This is a 36 week ,multi-center, open labeled, randomized controlled trial to assess the effect of two different treatment regimens of Biphasic Insulin Aspart 30 on glycaemic control (as measured by HbA1c) in subjects with type 2 diabetes not achieving glycaemic targets on Oral Antidiabetic Drugs. The study has three treatment phases for both treatment arms. Both study arms will be treated with Biphasic Insulin Aspart 30 treatment strategies, that are either started once daily with pre-breakfast dose or started with once daily pre-dinner dose. And then intensified to BID (two times a day) or TID (three times a day) if glycaemic control is not achieved for both groups, within three 12 weeks of treatment phases by titrating according to SMBG (Self Measurement of Blood Glucose) levels. All subjects will complete 36 weeks/ three phases of treatment. The patients achieving glycaemic control at visit 8 (week 11, end of phase I), may also be intensified to twice daily, if patient is did not achieve the target HbA1c <7.0 % at visit 15 (week 23 end of phase II). HbA1c will be measured at visits 8, 15 and 23 (11, 23 and 36 weeks). In this way, the trial will determine how many subjects achieved target HbA1c with once a day, bid (twice a day) or tid (three time s day) of Biphasic Insulin Aspart 30 for both arms. The percentage of subjects achieving target HbA1c will be assessed at weeks 8, 15 and 36 for both treatment regimens.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104266297N1**

Registration date: **2011-07-10, 1390/04/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-10, 1390/04/19

Registrant information

Name

Sayeh Tadayon

Name of organization / entity

Novo Nordisk Pars

Country

Iran (Islamic Republic of)

Phone

+98 88645225

Email address

sayt@novonordisk.com

Recruitment status

Recruitment complete

Funding source

Sponsored by Novo Nordisk A/S

Expected recruitment start date

2011-03-06, 1389/12/15

Expected recruitment end date

2012-01-01, 1390/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Safety Comparison of Two Different Biphasic Insulin Aspart 30 Treatment Initiation Regimens Followed by intensification in Subjects with Type 2 Diabetes Mellitus Not Achieving Glycaemic Targets on Oral Anti Diabetic Drugs alone in Iran

Public title

BIAsp-3858

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria 1. Informed consent obtained before any trial-related activities. (Trial-related activities are any procedure that would not have been performed during normal management of the subject.) 2. Diagnosed with type 2 diabetes for a minimum of 6 months prior to Visit 1. 3. Male or female, age ≥ 18 years of age 4. HbA1c $\geq 7.0\%$ - $\leq 11\%$ at screening 5. Subject is insulin naïve (short-term insulin treatment of up to 14 days is allowed) 6. An antidiabetic regimen that has been stable for at least 3 months prior to screening 7. An antidiabetic regimen that includes a minimum of 2 OADs 8. OADs dosed at $\geq 50\%$ of the maximum recommended dose 9. Able and willing to adhere to the therapeutic regimen 10. Able and willing to perform SMBG testing as per protocol 11. Ophthalmoscopic examination within 12 months prior to screening Exclusion Criteria 1. Known or suspected hypersensitivity to trial product(s) or related products 2. Females of childbearing potential who are pregnant, breast-feeding or intend to become pregnant or are not using adequate contraceptive methods (adequate contraceptive measures as required by local law or practice). 3. The receipt of any investigational medicinal product within one month prior to this trial. 4. Suffer from a life threatening disease (cancer) 5. Active proliferative retinopathy or maculopathy requiring treatment within 6 months prior to Screening 6. Cardiac disease: class III or IV CHF, unstable angina, and or any myocardial infarction (treated or untreated) within 6 months prior to screening 7. Hepatic insufficiency (Alanine aminotransferase (ALT) or Aspartate aminotransferase (AST) > 2 times the central laboratory's upper reference limit) 8. Renal insufficiency (serum creatinine > 1.6 mg/dl for males; 1.4 mg/dl for females) 9. Recurrent hypoglycaemia or hypoglycaemic unawareness 10. Anemia (haemoglobin < 10 mg/dl) 11. Use of concomitant medications which may alter glucose metabolism including but not limited to: systemic or inhaled glucocorticoids, anabolic steroids, non-selective beta-blockers 12. Known or suspected abuse of alcohol, narcotics or illicit substances 13. Mental incapacity, psychiatric disorder, unwillingness or language barriers precluding adequate understanding or co-operation, including subjects not able to read or write 14. Any conditions that the Investigator judges would interfere with trial participation or evaluation of the results

AgeFrom **18 years** old**Gender**

Both

Phase

4

Groups that have been masked*No information***Sample size**Target sample size: **300****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

clinicaltrial.gov

Secondary trial Id

NCT01215435

Registration date

2010-10-01, 1389/07/09

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Endocrine Research Centre for Shaheed Beheshti University of Medical Sciences

Street address

Research Institute For Endocrine Sciences, #24 Parvaneh st, Yemen st, Chamran Exp

City

Tehran

Postal code**Approval date**

2010-08-10, 1389/05/19

Ethics committee reference number

313EC89/05/13

2**Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Nect to Milad Tower, West Hemmat Exp. Way

City

Tehran

Postal code**Approval date**

2010-08-08, 1389/05/17

Ethics committee reference number

892/4

3**Ethics committee****Name of ethics committee**

National Ethics Committee for Research in Medical Sciences

Street address

3rd Floor, Deputy of Research, Azadi Avenue, Tehran

City

Tehran

Postal code**Approval date**

2010-11-07, 1389/08/16

Ethics committee reference number

30/P89K-1

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus Type II

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus type II

Primary outcomes

1

Description

HbA1c levels

Timepoint

visit 8 (end of phase I)

Method of measurement

Laboratory Assessment

Secondary outcomes

1

Description

Percentage of subjects achieving HbA1c < 7%

Timepoint

visit 8, 15 and 23.

Method of measurement

Laboratory Assessment

2

Description

FPG levels

Timepoint

end of phase I, II and III, measured at visits 8, 15, 23

Method of measurement

Laboratory Assessment

3

Description

8-point plasma glucose profiles

Timepoint

levels at visits 9, 16, 23

Method of measurement

Subcutaneous Measurement of Blood Glucose

4

Description

HbA1c level

Timepoint

visits 15 and 23

Method of measurement

Laboratory Assessment

Intervention groups

1

Description

Insulin therapy is indicated for the treatment of hyperglycaemia in diabetes mellitus. The purpose of this trial is to make a comparison of two different treatment strategies with Biphasic insulin Aspart 30, in terms of efficacy on HbA1c levels in subjects who are not controlled on Oral Anti Diabetic therapy. Biphasic Insulin Aspart 30 will be used subcutaneously according to dosage regimen that given by the titration guideline. In the first intervention subjects start treatment with Biphasic Insulin Aspart 30 15 minutes before breakfast (starting with 12 units).

Category

Treatment - Drugs

2

Description

Insulin therapy is indicated for the treatment of hyperglycaemia in diabetes mellitus. The purpose of this trial is to make a comparison of two different treatment strategies with Biphasic insulin Aspart 30, in terms of efficacy on HbA1c levels in subjects who are not controlled on Oral Anti Diabetic therapy. Biphasic Insulin Aspart 30 will be used subcutaneously according to dosage regimen that given by the titration guideline. In the second intervention subjects start treatment with Biphasic Insulin Aspart 30 15 minutes before dinner (starting with 12 units).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Loghman Hakim Hospital

Full name of responsible person**Street address****City**

Tehran

2

Recruitment center**Name of recruitment center**

Firoozgar Hospital

Full name of responsible person

Street address

City

Tehran

Country of origin

Type of organization providing the funding

empty

3

Recruitment center

Name of recruitment center

Labafi Nejad Hospital

Full name of responsible person

Street address

City

Tehran

4

Recruitment center

Name of recruitment center

Erfan Hospital

Full name of responsible person

Street address

City

Tehran

5

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Novo Nordisk A/S

Full name of responsible person

Ehsan Parvaresh

Street address

11th Floor, Kian Tower, No 1387, Upper Dastjerdi St,
Vali Asr St.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Novo Nordisk A/S

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Novo Nordisk

Full name of responsible person

Sayeh Tadayon

Position

Clinical Research Associate/ Medical Doctor

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Novo Nordisk Pars

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Position

Clinical Research Associate / Medical Doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty