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 Measurment 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 ≥ 7.0 %- ≤ 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 ≥ 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. Opthalmoscopic 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
Age
From **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 phasel, 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 Iinsulin 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 minuets 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 Iinsulin 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 minuets before dinner (starting with 12 units).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospitan
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

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
Country of origin
Type of organization providing the 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

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Full name of responsible person
Sayeh Tadayon
Position
Medical Manager/ Medical Doctor
Other areas of specialty/work
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Fax
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Novo Nordisk Pars
Full name of responsible person
Sayeh Tadayon
Position
Clinical Research Associate / Medical Doctor

Other areas of specialty/work
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Fax
Email
sayt@novonordisk.com
Web page address

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