Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Phase III, Randomized, Parallel Groups, Open-label, Active-control, Non-inferiority Clinical Trial on Efficacy and Safety of Dulagtima (Dulaglutide by Artiman Pharmed Alborz) in Comparison with Trulicity® (Dulaglutide by Eli Lilly) in the Treatment of Type 2 Diabetic Patients

Protocol summary

Study aim
Non-inferiority evaluation of efficacy and safety of Dulagtima (dulaglutide produced by Artiman Pharm Alborz) compared to Trulicity® (dulaglutide produced by Eli Lilly) in control of type 2 diabetes

Design
Phase 3 clinical trial on 200 patients, randomized, parallel, open-label, active control. Sequence of randomization of patients between two groups with sequential and random blocks of 6, at a ratio of 1:2 (4 Dulagtima codes and 2 Trulicity codes in each block) is performed before patient selection for each site.

Settings and conduct
Patients with T2DM, after physician assessment, full study information, and signing consent, will be randomly assigned to test or control groups. Medications will be given subcutaneously once a week; the initial 0.75 mg dose will increase to 1.5 mg after 4 weeks with investigator approval. Blood samples will be collected at the start and after 18 weeks to assess HbA1c, fasting glucose, and other factors. Side effects will be recorded during visits or calls. This study will be conducted in selected diabetes clinics in Tehran after legal approvals

Participants/Inclusion and exclusion criteria
Inclusion criteria: Type 2 diabetes, Age 25-70 years, both sexes, consent to participate, 7.5%≤HbA1c≤10%, 25<BMI≤40. Exclusion criteria: Participation in another trial, GLP-1/DPP4 agonists use or change in diabetes medicines in the past 3 months, bolus insulin use, hospitalization or cardiovascular issues in the past 6 months, gastroparesis, bypass surgery, obesity or organ transplant, pancreatitis, medullary thyroid carcinoma, multiple endocrine neoplasia type 2, blood disorders, type 1 diabetes, pregnancy, lactation, retinopathy, renal failure, liver cirrhosis, ALT>3x normal, active malignancy or cancer recovery within 5 years

Intervention groups
Dulagtima (test) and Trulicity (control) both for 18 wks

Main outcome variables
Changes in glycosylated hemoglobin (HbA1C)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101012004920N12**
Registration date: **2024-09-03, 1403/06/13**
Registration timing: **prospective**

Last update: **2024-09-03, 1403/06/13**
Update count: **0**

Registration date
2024-09-03, 1403/06/13

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-22, 1403/08/01

Expected recruitment end date
2025-10-23, 1404/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Phase III, Randomized, Parallel Groups, Open-label, Active-control, Non-inferiority Clinical Trial on Efficacy and Safety of Dulagtima (Dulaglutide by Artiman Pharmed Alborz) in Comparison with Trulicity® (Dulaglutide by Eli Lilly) in the Treatment of Type 2 Diabetic Patients

Public title
Phase III Clinical Trial, Efficacy and Safety of Dulagtima in Comparison with Trulicity®
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with type 2 diabetes for at least 3 months Age between 25 and 70 years when entering the study, applicable to both sexes. Consent to participate in the study and sign a written informed consent form 7.5 % ≤ HbA1c ≤ 10% BMI more than 25 and equal or less than 40
Exclusion criteria:
Patients who intend to participate in another clinical trial during the study. Patients with type 1 diabetes Patients who have used other GLP-1 or DPP4 receptor agonist drugs within 3 months before the study. Patients who are currently using bolus insulin for diabetes treatment (basal insulin use is allowed). Patients who have had a change in dose or type of diabetes medication in the 3 months prior to entering the study Patients who have had one or more hospitalizations in the past 6 months due to lack of diabetes control. Abnormalities in gastric emptying, such as severe diabetic gastroparesis or gastric outlet obstruction, and plans for bypass or obesity-related surgeries during the study. Have a history of a heart or brain problem such as heart attack, chest pain (except heartburn), angioplasty or stenting, or stroke within 6 months before screening. Patients with severe renal failure (GFR <30 mL/minute/1.73 m2) Patients with liver cirrhosis or alanine transaminase (ALT) levels greater than 3 times the upper limit of normal. Patients with active malignancy or patients who are recovering from cancer in less than 5 years. Patients with a history of organ transplantation. Patients with a blood disorder that affects blood sugar measurements or laboratory samples Pregnant or lactating women or women who intend to become pregnant during the study period History of chronic or acute pancreatitis. Personal or family history of medullary thyroid carcinoma or personal history of multiple endocrine neoplasia syndrome type 2 Diagnosis of proliferative retinopathy or maculopathy
Age
From **25 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Before starting the recruitment process at each site, a numerical sequence for randomizing patients between two treatment groups is created using successive and random permuted blocks, with a block size of 6. The randomization is done in a 1:2 ratio, so each block of 6, randomly includes 4 codes for Dulaglutima and 2 for Trulicity. The generated random sequence is placed at the study sites. Each randomization code corresponds to a drug package (one of the two intervention groups), which is labeled and stored in the drug stock at the study site. After confirming the patient’s eligibility and obtaining informed consent, the corresponding drug, based on the order specified in the randomization table, is injected into the patient.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee for Research of Medical School - Tehran University of Medical Sciences
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Northern Entrance of Tehran University - PourSina St. - Keshavarz Blv.
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Postal code
1461884513
Approval date
2024-08-28, 1403/06/07
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.223

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11.9
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Glycosylated hemoglobin (HbA1C) change at week 18 compared to baseline
Timepoint
At the beginning and week 18
Method of measurement
Measuring by the central laboratory

Secondary outcomes

1

Description
Glycemic control (change in fasting blood sugar) at week 18 compared to the baseline
Timepoint
At the baseline and week 18
Method of measurement
Measuring of fasting blood sugar by the central laboratory

2

Description
Weight changes in the 18th week compared to the baseline state
Timepoint
At the baseline and week 18
Method of measurement
Using digital weight scale

3

Description
The proportion of patients who achieve an HbA1c of less than 7
Timepoint
Week 18
Method of measurement
Dichotomized HbA1c level at the cut-off of 7

4

Description
Frequency of side effects or serious side effects during 18 weeks
Timepoint
7 days after the screening visit, 1+7 days after the 1st visit, 3+28 days after the 1st visit, 3+42 days after the 1st visit, 3+56 days after the 1st visit, 3+70 days after the visit 1, 84+3 days after visit 1, 98+3 days after visit 1, 112+3 days after visit 1, 126+3 days after visit 1
Method of measurement
Self-reporting by the individual during in-person and phone visits

5

Description
Frequency of patients with anti-drug antibodies
Timepoint
Week 18
Method of measurement
Elisa test on patients' sera

Intervention groups

1

Description
Intervention group: (Dulaglutide manufactured by Artiman Pharmed Alborz Company) for 18 weeks, as a subcutaneous injection first with a dose of 0.75 mg for 4 weeks and then a dose of 1.5 mg for the next 14 weeks
Category
Treatment - Drugs

2

Description
Control group: Trulicity (Dulaglutide manufactured by Eli Lilly) for 18 weeks, as a subcutaneous injection first with a dose of 0.75 mg for 4 weeks and then a dose of 1.5 mg for the next 14 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes and Endocrine Clinic
Full name of responsible person
Alireza Esteghamati
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2

Recruitment center

Name of recruitment center
Dr. Farhad Hossein Panah's office

Full name of responsible person
Farhad Hossein Panah

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3

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Name of recruitment center
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4

Recruitment center

Name of recruitment center
Dr. Majid Valizadeh's Office

Full name of responsible person
Majid Valizadeh

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5

Recruitment center

Name of recruitment center
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Full name of responsible person
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6

Recruitment center

Name of recruitment center
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7

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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artiman Pharmed Alborz Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Ramin Heshmat
Position
Professor, Head of Chronic Diseases Research Center
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available