

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of efficacy of moderater-acting insulin (NPH) manufactured by Ronak Daru (Ronulin ®) with manufactured by Exir (Lansulin®) in reducing fasting blood sugar in patients with type 2 diabetes

Protocol summary

Summary

The main goal of study is Comparison of efficacy of NPH manufactured by Ronak Daru (Ronulin ®) with manufactured by Exir (Lansulin®) in reducing fasting blood sugar in patients with type 2 diabetes. Study is randomized, single centre, and not blind that was done on 196 patients with type 2 diabetes that treated with insulin with or without oral agent. This patients treat with less than 1.4 U/kg/d well, is more than 18 years old, isn't obese, and don't have any complication. We take Informed consent from them. Duration of study is 3 months for any group. Patients enrolled in any group accidentally. Dosage of regular insulin or NPH insulin is as before. NPH insulin of two groups is Lansulin. Patients is visited by physician during the study every 2 weeks and is checked for FBS, 2 hr postprandial, and acute complications such as hypoglycemia or hyperglycemia. The primary outcome is HbA1c after survey. The secondary outcome is weight and insulin dosage difference and acute complications(hypoglycemia and hyperglycemia).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040912938N2**

Registration date: **2013-05-01, 1392/02/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-01, 1392/02/11

Registrant information

Name

Zahra Kourorian

Name of organization / entity

Ronak Daru Company of Pharmacy

Country

Iran (Islamic Republic of)

Phone

+98 21 8898 9441

Email address

zkourorian@irimc.org

Recruitment status

Recruitment complete

Funding source

Ronak Daru Company of pharmacy

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of moderater-acting insulin (NPH) manufactured by Ronak Daru (Ronulin ®) with manufactured by Exir (Lansulin®) in reducing fasting blood sugar in patients with type 2 diabetes

Public title

NPH Insulin efficacy in diabetes management

Purpose

Health service research

Inclusion/Exclusion criteria

inclusion criteria:1- diabetic patients type 2 treated with insulin with or without oral drug. 2-100mg/dl< FBS <250mg/dl. 3- 7< HbA1c< 9. 4- male or female with age

> 18 years old*. 5-(BMI≤30)kg/m2.*We have enrolled patients with age more than 18 years, according to reference 17, 18, 19, and 20. Age don't be considered as a confounding factor because study has randomized design. exclusion criteria: 1- microvascular and macrovascular complications. 2- hypoglycemia(BS<70mg/dl) or hyperglycemia(BS>250mg/dl). 3-pregnancy or Breastfeeding. 4-use of glucocorticoides or any drug that lead hyperglycemia. 5- uncontrolled HTN(BP>180/105). 6- insulin allergy. 7-use of more than 1.4 U/kg/d insulin. 8-Cr>2 mg/dl or LFT>twofold normal range. 9- Patient withdrew from the study.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **196**

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**

empty

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

Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences-Molla Sadra Ave, Vanak Sq

City

Tehran

Postal code**Approval date**

2012-10-17, 1391/07/26

Ethics committee reference number

340/22/س

Health conditions studied**1****Description of health condition studied**

Diabete

ICD-10 code

E10,E11,E1

ICD-10 code description

Diabetes mellitus

Primary outcomes**1****Description**

mean of HbA1c

Timepoint

before and after of study

Method of measurement

HPLC assay

Secondary outcomes**1****Description**

dosage of insulin

Timepoint

before and after of study

Method of measurement

unit

2**Description**

hyperglycemia

Timepoint

during study

Method of measurement

with laboratory or SMBG

3**Description**

hypoglycemia

Timepoint

during study

Method of measurement

with laboratory or SMBG

4**Description**

weight change

Timepoint

before and afterof study

Method of measurement

scale

Intervention groups

1

Description

Intervention:NPH manufactured by Ronak Daru (Ronulin®) through FBS=90-130 mg and HbA1c<7 during 3 months.

Category

Treatment - Drugs

2

Description

control: NPH manufactured by Exir (Lansulin®) through target FBS= 90-130 mg/dl and HbA1c<7 during 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Dr nahid Khailil

Street address

Baqiyatallah University of Medical Sciences,Molla Sadra Ave, Vanak Sq

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ronak Daru Company of pharmacy

Full name of responsible person

Dr zahra Kourorian

Street address

fatemi AVE,hashtbehesht str,ardeshir str,No 10/3

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ronak Daru Company of pharmacy

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

chemical injery research center

Full name of responsible person

Dr yues Panahi

Position

head of chemical injery research center/Associate of Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences, internal medicine department

Full name of responsible person

Dr nahid Khalili

Position

Assistant of Professor of endocrinology

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ronak Daru Company of pharmacy

Full name of responsible person

Dr zahra Kourorian

Position

Manager of clinical trial/ General Physician

Other areas of specialty/work

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Fax**Email**

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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