Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of efficacy of short-acting insulin (Regular) manufactured by Ronak Daru (Ronulin ®) with manufactured by Exir (Lansulin®) in reducing blood sugar after meals in patients with type 2 diabete

Protocol summary

Summary

The main goal of study is Comparison of efficacy of short-acting insulin (Regular) manufactured by Ronak Daru (Ronulin ®) with manufactured by Exir (Lansulin®) in reducing blood sugar after meals in patients with type 2 diabetes. Study is randomized, single centre, cross-over, and not blind that was done on 40 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 (first 3 months for Ronalin or Lansulin and then inverse).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: **IRCT2013040812938N1**
Registration date: **2013-04-24, 1392/02/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-04-24, 1392/02/04

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 short-acting insulin (Regular) manufactured by Ronak Daru (Ronulin ®) with manufactured by Exir (Lansulin®) in reducing blood sugar after meals in patients with type 2 diabete

Public title

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<45mg/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-iinsulin allergy. 7-use of more than 1.4 U/kg/d insulin. 8-نرمال 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: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Baqiyatallah University of Medical Sciences

Street address
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 in the end of study

Timepoint
HbA1c levels before and after of any intervation

Method of measurement
at before and after of intervation by laboratory with HPLC assay

Secondary outcomes

1

Description
hypoglycemia

Timepoint
during study

Method of measurement
Bionime Glucometer

2

Description
weight changes

Timepoint
before and after of intervation

Method of measurement
scale

3

Description
hyperglycemia

Timepoint
during study

Method of measurement
Bionime glucometer

4

Description
insulin dosage

Timepoint
during study

Method of measurement
unit

Intervention groups

1

Description
control: manufactured by Exir (Lansulin®)

Category
Treatment - Drugs

2

Description
Ronak Daru (Ronulin ®)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Chemical Injury Research Center
Full name of responsible person
Dr nahid Khalili
Street address
Baqiyatalla Hospital, Molla Sadra Ave, Vanak Sq
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ronak Daru Company of pharmacy
Full name of responsible person
Dr Zahra Kororian
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 Injury Research Center
Full name of responsible person
Dr yunes Panahi
Position
Associate of Professor/head of Chemical Injury Research Center
Other areas of specialty/work
Street address
Baqiyatallah University of Medical Sciences, Molla Sadra Ave, Vanak Sq
City
Tehran
Postal code
Phone
+98 21 8821 1524
Fax
Email
yunespanahi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Internal Medicine Department
Full name of responsible person
Dr nahid Khalili
Position
Assistant of Professor
Other areas of specialty/work
Street address
Baqiyatallah University of Medical Sciences,Molla Sadra Ave, Vanak Sq
City
Tehran
Postal code
Phone
+98 21 8126 3988
Fax
+98 21 8126 3989
Email
nkhalili09@gmail.com
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
General Physician/Manager of Clinical trials
Other areas of specialty/work
Street address
Fatemi Ave, Hashtbehesht Str,Ardeshir Str,No 10/3
City
Tehran
Postal code
1414713461
Phone
+98 21 8898 9441
Fax

+98 88989443

Email

zkourorian@razi.tums.ac.irzkourorian@irimc.org

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