

# 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**

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**Full name of responsible person**

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**Position**

Assistant of Professor of endocrinology

**Other areas of specialty/work**

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Ronak Daru Company of pharmacy

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Dr zahra Kourorian

**Position**

Manager of clinical trial/ General Physician

**Other areas of specialty/work**

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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*