

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of Insulin Glargine and Detemir on Hormone Factors Affecting Appetite in Patients with Type 1 Diabetes

#### Protocol summary

##### Study aim

compare the insulin glargine and detemir on hormone factors affecting appetite in type 1 diabetic patients

##### Design

A simple randomization (according to table of random number), with a 2 parallel group, N=41 (first intervention group1 n=21 second intervention group n=20), Not blinded, Phase 3

##### Settings and conduct

A total of 41 children with new case of type 1 diabetes under 18 years that hospitalized in Ali Asghar Children's Hospital in April to August 2019. Patients were randomly assigned into two groups as insulin Glargine (n=21) and insulin Detemir(n=20) during 3 months. Insulin was given by subcutaneous injection at 30-50% of the patient's daily requirement (according to age and clinical response).

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Parent's Consent to participate in this study, new cases of children with type1 diabetes, Children under 18 years old Exclusion criteria: No Parental consent, Non-cooperation until the end of the study (Discontinuation of use)

##### Intervention groups

Intervention group 1: Includes new cases of type 1 diabetes that hospitalized. In this group, samples (n=21) received insulin Glargine for 3 months. Insulin Glargine was given to the patients once a day, subcutaneous injection and base on of 30-50% of the patient's daily requirement (based on age and clinical response). Intervention group 2: Includes new cases of type 1 diabetes that hospitalized. In this group, samples (n=20) received insulin Detemir for 3 months. Insulin Detemir was given to the patients twice a day, subcutaneous injection and base on of 30-50% of the patient's daily requirement (based on age and clinical response).

##### Main outcome variables

Rate of Factors affecting appetite (increase/decrease)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191208045651N1**

Registration date: **2019-12-23, 1398/10/02**

Registration timing: **retrospective**

Last update: **2019-12-23, 1398/10/02**

Update count: **0**

##### Registration date

2019-12-23, 1398/10/02

##### Registrant information

##### Name

Hosein Momeni

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2304 6253

##### Email address

momeni.h@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-30, 1398/02/10

##### Expected recruitment end date

2019-08-01, 1398/05/10

##### Actual recruitment start date

2019-04-30, 1398/02/10

##### Actual recruitment end date

2019-08-01, 1398/05/10

##### Trial completion date

2019-08-01, 1398/05/10

##### Scientific title

Comparison of Insulin Glargine and Detemir on Hormone Factors Affecting Appetite in Patients with Type 1 Diabetes

#### Public title

Comparison of Insulin Glargine and Detemir on Hormone Factors Affecting Appetite in Patients with Type 1 Diabetes

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Parent's Consent new cases of children with type1 diabetes Children under 18 years old.

##### Exclusion criteria:

No Parental consent Non-cooperation until the end of the study (Discontinuation of use)

#### Age

From **1 year** old to **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **41**

Actual sample size reached: **41**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

41 children with new case of diabetes type 1 assigned with simple randomization, according to the table of random number and individual randomization unit. 21 children in the first intervention group (insulin glargine) and 20 (insulin Detemir) neonates in the second intervention group were selected. In this study, do not allocation concealment.

#### 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

Ethics committee of Iran University of Medical Sciences

##### Street address

No. 193, Vahid dastgerdy Ave, Modares highway, Aliasghar Children Hospital

#### City

Tehran

#### Province

Tehran

#### Postal code

1919816766

#### Approval date

2019-04-23, 1398/02/03

#### Ethics committee reference number

IR.IUMS.FMD.REC.1398.052

## Health conditions studied

### 1

#### Description of health condition studied

Type 1 Diabetes

#### ICD-10 code

E10

#### ICD-10 code description

Type 1 Diabetes mellitus

## Primary outcomes

### 1

#### Description

Increase or decrease in Leptin hormone

#### Timepoint

before taking Insulin and 3 months after taking it

#### Method of measurement

Laboratory Test (Appetite hormones test)

### 2

#### Description

Increase or decrease in Gherlin hormone

#### Timepoint

before taking Insulin and 3 months after taking it

#### Method of measurement

Laboratory Test (Appetite hormones test)

### 3

#### Description

Increase or decrease in AGRP hormone

#### Timepoint

before taking Insulin and 3 months after taking it

#### Method of measurement

Laboratory Test (Appetite hormones test)

### 4

#### Description

Increase or decrease in PYY 3-36 hormone

#### Timepoint

before taking Insulin and 3 months after taking it

#### Method of measurement

Laboratory Test (Appetite hormones test)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Includes new cases of type 1 diabetes that hospitalized. In this group, samples (n=21) received insulin Glargine for 3 months. Insulin Glargine was given to the patients once a day, subcutaneous injection and base on of 30-50% of the patient's daily requirement (based on age and clinical response).

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Includes new cases of type 1 diabetes that hospitalized. In this group, samples (n=2۷) received insulin Detemir for 3 months. Insulin Detemir was given to the patients twice a day, subcutaneous injection and base on of 30-50% of the patient's daily requirement (based on age and clinical response).

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ali Asghar Children's hospital

##### Full name of responsible person

Hosein Momeni

##### Street address

No. 193, Vahid Dastgerdy Ave, Modares Highway, Ali Asghar Children's Hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1919816766

##### Phone

+98 21 2304 6253

##### Email

dr.momeni.p@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Abbas Motevalian

#### Street address

Shahid Hemmat Highway, Iran University of Medical Sciences

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۴۹۶۱۴۵۳۵

#### Phone

+98 21 86701

#### Email

motevalian.a@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Hosein Momeni

##### Position

fellow

##### Latest degree

Specialist

##### Other areas of specialty/work

Pediatrics

##### Street address

No. 193, Vahid dastgerdy Ave, Modares highway, Aliasghar Children Hospital

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##### Phone

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##### Email

momeni.h@iums.ac.ir

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hosein Momeni

**Position**

Fellow

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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Asghar Children's Hospital

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**Province**

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**Email**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hosein Momeni

**Position**

Fellow

**Latest degree**

Specialist

### **Other areas of specialty/work**

Pediatrics

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### **Postal code**

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### **Phone**

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### **Email**

dr.momeni.p@gmail.com

## **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