Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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=2ج) 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=2خ) 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
City
Tehran
Province
Tehran
Postal code
1919816766
Phone
+98 21 2304 6252
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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Province
Tehran

Postal code
1919816766

Phone
+98 21 2304 6253

Email
dr.momeni.p@gmail.com

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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+98 21 2304 6253

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