

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of Once- Versus Twice-Daily Administration of long-acting insulin Detemir in children with type 1 diabetes

Protocol summary

Study aim

Comparison of the efficacy of Once- Versus Twice-Daily Administration of insulin Detemir in children with type 1 diabetes.

Design

For patients, the schedule is once or twice a day for insulin Detemir plus a short-acting insulin for food. Blocks randomization method and 4 blocks were used including 2 participants in intervention group 1 and 2 participants in intervention group 2. sample size : 25 for each group

Settings and conduct

The first month : teaching the patient and adjusting the dose of insulin. Before starting the study and at the end of the fourth month,: HbA1c is measured at the Laboratory of the children medical center and by staff who are unaware of the research The height and weight at the beginning and the end of the study and the insulin dose required at the end of the study will be recorded. At the end, the results of the two groups will be compared. In the course of the study, patients are monitored for events such as hypoglycemia or need for hospitalization due to the lack of proper control of the disease. It will be available 24 hours a day through a dedicated telephone number for patients and an awareness of their sugar control status, measured in the home and recorded in the sugar chart and sent via the Telegram.

Participants/Inclusion and exclusion criteria

Inclusion Diabetes mellitus type 1 (according to ISPAD 2014 criteria). Age at diagnosis :2-6 years old Lasting 1 year since diagnosis Desire to use Detemir Exclusion: The use of drugs that are effective on controlling diabetes at any time during the duration of the study.

Intervention groups

For patients, the schedule is once or twice a day for insulin Detemir plus a short-acting insulin for food.

Main outcome variables

HbA1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181106041574N1**

Registration date: **2019-01-16, 1397/10/26**

Registration timing: **prospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **0**

Registration date

2019-01-16, 1397/10/26

Registrant information

Name

Reza Tavakolizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5517 6814

Email address

rtavakolizadeh@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Once- Versus Twice-Daily Administration of long-acting insulin Detemir in children with type 1 diabetes	
Public title	Comparison of Once- Versus Twice-Daily Administration of long-acting insulin Detemir in children with type 1 diabetes
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Diabetes mellitus type 1 (according to ISPAD 2014 criteria) Age at diagnosis: 2-6 years old Lasting at least 1 year since diagnosis Desire to use insulin Detemir
Exclusion criteria:	The use of drugs that are effective on controlling diabetes
Age	From 24 months old
Gender	Both
Phase	3
Groups that have been masked	- Investigator - Outcome assessor - Data analyser
Sample size	Target sample size: 50
Randomization (investigator's opinion)	Randomized
Randomization description	Blocks randomization method. Block randomization method with random selection of blocks size (4 and 8) will be used, Blocked Randomization with Randomly Selected Block Sizes will be performed. The number of samples assigned to each group in each block is equal. After the random sequences of groups A and B are listed in the blocks, they are numbered. In order to Allocation concealment, to the sample size, the sealed opaque envelopes is provided. To keep the contents hidden from the outside of the envelope, Each of the sequences created on the card is recorded and the cards are inserted into the envelopes respectively. The outer surface of the envelopes is also numbered in the same way. At the time of the sampling, one of the envelopes is opened according to the order of entry of qualified participants, and the designated group of the participant is determined.
Blinding (investigator's opinion)	Double blinded
Blinding description	laboratory personel and data analizer are blind.
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Children's Medical Center, Tehran University of Medical Sciences

Street address

No 62, Dr. Gharib St., Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۵۱

Approval date

2018-07-14, 1397/04/23

Ethics committee reference number

IR.TUMS.CHMC.REC.1397.014

Health conditions studied

1

Description of health condition studied

Diabetes mellitus type 1

ICD-10 code

E10.9

ICD-10 code description

Type 1 diabetes mellitus without complications

Primary outcomes

1

Description

HbA1c

Timepoint

3 Months

Method of measurement

lab

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The insulin used is (Levemir®; NovoNordisk A / S, Bagsvaerd, Denmark, 100 U / ml). For patients, the schedule is once a day for insulin Detemir plus a short-acting insulin for food. The whole study period is 4 months. The first month will be spent teaching the patient and adjusting the dose of

insulin. Before starting the study and at the end of the fourth month, the patient's HbA1c is measured. The height and weight at the beginning and the end of the study and the insulin dose required at the end of the study will be recorded. HbA1c measurements are carried out at the Laboratory of the children medical center and by staff who are unaware of the research, and the rest are done at Endocrine clinic of medical center. In the course of the study, patients are monitored for events such as hypoglycemia or need for hospitalization due to the lack of proper control of the disease.

Category

Treatment - Drugs

2

Description

Intervention group: The insulin used is (Levemir®; NovoNordisk A / S, Bagsvaerd, Denmark, 100 U / ml). For patients, the schedule is twice a day for insulin Detemir plus a short-acting insulin for food. The whole study period is 4 months. The first month will be spent teaching the patient and adjusting the dose of insulin. Before starting the study and at the end of the fourth month, the patient's HbA1c is measured. The height and weight at the beginning and the end of the study and the insulin dose required at the end of the study will be recorded. HbA1c measurements are carried out at the Laboratory of the children medical center and by staff who are unaware of the research, and the rest are done at Endocrine clinic of medical center. At the end, the results of the two groups will be compared. In the course of the study, patients are monitored for events such as hypoglycemia or need for hospitalization due to the lack of proper control of the disease.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical center

Full name of responsible person

Reza Tavakolizadeh

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Children's Medical Center, 62 Qarib St. , Keshavarz Blvd., Tehran 14194, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Floor 6, Central building of Tehran University, Qods street, Keshavarz Blv., Tehran, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Reza Tavakolizadeh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The study protocol and informed consent form will be shared.

When the data will become available and for how long

Up to one year after printing results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Use in similar studies or for meta-analysis studies

From where data/document is obtainable

Corresponding author of article

What processes are involved for a request to access data/document

Via an academic email, study must be registered and have a valid ethics code.

Comments