Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of preprandial and postprandial injection of Insulin Aspart on glycemic control of type 1 diabetic children

Protocol summary

Study aim
Comparison of the effect of of preprandial and postprandial injection of Insulin Aspart on glycemic control of children with diabetes mellitus type 1

Design
Two arm crossover group on 60 patients

Settings and conduct
The target population is patients aged 6 to 17 years with type 1 diabetes who are treated with basal insulin and insulin Aspart as short-acting insulin, but are poor controlled. Sixty 6-17 year old patients with mentioned conditions who are admitted in the pediatric endocrinology clinic of Hazrat Rasoul centre are selected and divided into two groups by convenient sampling. FBS, 2hpp BS and HGA1C of all patients will be checked. Lantus insulin is given to both groups as the basal insulin. The first group will inject insulin Aspart 15 minutes before and the second group will inject the insulin Aspart 15 minutes after each meal subcutaneously. Patients will be visited every 2 weeks by a pediatric endocrinologist and an assistant. if needed, the patient's insulin dose will be changed. After 3 months, the patients' glucose profiles are checked and compared.Then, the 2 groups are replaced. after 3 months, BS profiles of the two groups will be evaluated and compared again.

Participants/Inclusion and exclusion criteria
6-17 year old children with poor controlled insulin dependent diabetes

Intervention groups
First of all patients' FBS, 2hpp BS and HGA1C will be check. Lantus insulin will be adminstered to both groups as the basal insulin. The first group will be recommended to inject insulin Aspart 15 minutes before and the second group 15 minutes after each meal subcutaneously. After 3 months, the patients' glucose profiles will be checked and compared.Then, the 2 groups are replaced and after 3 months, the BS profiles of the 2 groups are checked and compared again.

Main outcome variables
FBS,2hpp BS,HGA1c

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210221050444N1**
Registration date: **2022-05-28, 1401/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-28, 1401/03/07**
Update count: **0**

Registration date
2022-05-28, 1401/03/07

Registrant information

Name
Payam Samei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3222 1833

Email address
samei.p@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-08-21, 1401/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of preprandial and postprandial injection of Insulin Aspart on glycemic control of type 1 diabetic children

Public title
Effect of Insulin Aspart in diabetic children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
6-17 year old children suffering from diabetic type 1
Under treatment by insulin poor controlled
Exclusion criteria:
Dissatisfaction of parents to participate in the project
Age
From **6 years** old to **17 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
Randomization (investigator's opinion)
Not 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
Ethics committee of Shahrekord University of Medical Sciences
Street address
Shahrekord University of Medical Science, Rahmatieh st., Shahrekord, Iran.
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۳۸۳۳۴۳۵
Approval date
2022-02-08, 1400/11/19
Ethics committee reference number
IR.SKUMS.REC.1400.231

Health conditions studied

1

Description of health condition studied
Diabetes Mellitus type 1
ICD-10 code
E10
ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
Time of the injection of Insulin
Timepoint
at the beginning and 3 months of beginning of the study
Method of measurement
Before and after meal

Secondary outcomes

1

Description
FBS
Timepoint
3 months and six months after the beginning of study
Method of measurement
blood sample

2

Description
2hpp BS
Timepoint
3 months and six months after the beginning of study
Method of measurement
blood sample

3

Description
HGA1C
Timepoint
3 months and six months after the beginning of study
Method of measurement
blood sample

4

Description
hypoglycemic episodes
Timepoint

Every time signs and symptoms of hypoglycemia occure

Method of measurement

Test by glucometere

Intervention groups

1

Description

Intervention group: subcutaneous injection of Insulin Aspart 15 minutes before taking of each meal for six months

Category

Treatment - Other

2

Description

Intervention group: subcutaneous injection of Insulin Aspart 15 minutes after taking of each meal for six months

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul clinic

Full name of responsible person

Payam Samei

Street address

Hazrat Rasoul clinic, Molavi st.,Shahrekord, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Esfandiar Heidarian

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Vice Chancellor for Research and Technology,Ayatollah Kashani Blv.,Shahrekord, 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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Payam Samei

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Pediatric Medicine Department, Saint Hajar Hospital, Parastar St., Shahrekord, Iran

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Person responsible for scientific inquiries

Contact

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Position

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Subspecialist
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Person responsible for updating data

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Shahre-kord University of Medical Sciences
Full name of responsible person
Payam Samei
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Patients dissatisfaction
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
Name of patients will not be published
When the data will become available and for how long
After analysis
To whom data/document is available
All of researchers
Under which criteria data/document could be used
For another researches(clinical trials, review articles and metanalysises)
From where data/document is obtainable
Payam Samei by this e-mail:Samei.p@skums.ac.ir
What processes are involved for a request to access data/document
Via Author's e-mail in at last 2 weeks
Comments