Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of adding long subcutaneous insulin to the standard treatment of diabetic ketoacidosis in children

Protocol summary

Study aim

Does the addition of long-acting subcutaneous insulin to the standard treatment of diabetic ketoacidosis reduce the time out of the acute phase?

Design

after providing a full explanation of the method and purpose of the research, the children's parents sign the consent form and the basic information is entered into a questionnaire. This information includes Age, weight, height, stage of puberty, history and severity of the disease .Patients are divided into one of the control and intervention groups using random block sampling method.Control group: receive short-term insulin drip (standard treatment). Intervention groups: In addition to receiving standard short-term insulin drip, they receive a long-acting subcutaneous insulin dose of 0.5 units per kilogram of child weight.In both groups,Time out of the acute phase and the occurrence of complications are recorded. Leaving the acute phase, ie serum pH level> 7.3 and HCO3> 15mEq / L, normal serum electrolytes, alertness and no vomiting. Blood glucose levels are measured and recorded by the glucometer every hour and the patients' blood glucose, sodium, potassium and VBG are measured every three hours.The results are compared and statistically analyzed in two groups.

Settings and conduct

Patients in all groups will be admitted to PICU from the time of admission to the time of exit from the acute phase and will be monitored continuously for possible complications and will be treated in case of complications.

Participants/Inclusion and exclusion criteria

nclusion criteria: 1• The patient is between 2 and 15 years old. 2• Children with acute diabetic ketoacidosis : o BS> 200 mg / dL o PH <7.30 o HCO3 <15 mEq /L o Urine ketone is positiv

Intervention groups

intervention groups: Adding two types of long-acting subcutaneous insulin to standard treatment of DKA

Main outcome variables

Time to exit the acute phase of diabetic ketoacidosis in hours

General information

Reason for update

Acronym

DKA

IRCT registration information

IRCT registration number: **IRCT20201125049485N1**
Registration date: **2021-01-05, 1399/10/16**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-05, 1399/10/16**
Update count: **0**

Registration date

2021-01-05, 1399/10/16

Registrant information

Name

Victoria Chegini

Name of organization / entity

Qums

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 2476

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-11, 1399/08/21

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adding long subcutaneous insulin to the standard treatment of diabetic ketoacidosis in children

Public title

Evaluation of the effect of adding long subcutaneous insulin to the standard treatment of diabetic ketoacidosis in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 2 to 15 years old acute diabetic ketoacidosis : BS> 200 mg / dL, PH <7.30 , HCO3 <15 mEq / L ,urinary ketone positive

Exclusion criteria:

• Reluctance to participate in the study

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

All children with diatotic ketoacidosis who are referred to Qazvin Children's Hospital for treatment are included in the study based on inclusion and exclusion criteria. Then patients are assigned to one of the 3 treatment groups based on the block random allocation table which is randomly assigned to the software. Therefore, we have 18 blocks, in each block of 6, the number of patients assigned to each treatment group is equal to 2.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the clinical caregiver (physician and nurse) is aware of the intervention due to the registration of the intervention in the physician's instructions , But the researcher, data analyzer, and outcome assessor do not know which patient is in the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

after providing a full explanation of the method and purpose of the research, the children's parents sign the consent form and the basic information is entered into a questionnaire. This information includes Age, weight, height, stage of puberty, history and severity of the disease . patients are divided into One of three groups of control and intervention using random block sampling method.Two intervention groups: Children who, in addition to receiving short-term standard insulin drip within the first 6 hours of treatment, receive a long-acting subcutaneous dose of Lantus or Detmirra at a rate of 0.5 units per kilogram of body weight .In both groups,Time out of the acute phase and the occurrence of complications are recorded , the duration of exit from the acute phase, the length of stay of the child in the intensive care unit and the occurrence of possible complications are reviewed and recorded. Exclusion from the acute phase in this study is a condition in which the serum level is PH> 7.3, HCO3> 15mEq / L, normal serum electrolytes, the patient is conscious and does not vomit. The serum level of patients' blood sugar is measured and recorded by the glucometer every hour and the level of blood sugar, sodium, potassium and VBG (Venus blood gas) of patients is measured and recorded by the laboratory every three hours. Finally, the collected data are compared with each other and the findings are reported. All patient information will remain confidential with the researchers and the findings of this study will be reported anonymously.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Blvd

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Province

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Postal code

15315-34199

Approval date

2020-11-11, 1399/08/21

Ethics committee reference number

IR.QUMS.REC.1399.315

Health conditions studied

1

Description of health condition studied

acute phase of diabetic ketoacidosis

ICD-10 code

E00-E89

ICD-10 code description

Endocrine, nutritional and metabolic diseases.

Primary outcomes

1

Description

Duration of exit from the acute phase of diabetic ketoacidosis.Exclusion from the acute phase in this study is a condition in which the serum level is PH> 7.30, HCO3> 15mEq / L, normal serum electrolytes, the patient is conscious and does not vomit

Timepoint

From the time of diagnosis of diabetic ketoacidosis to the time of exit from the acute phase

Method of measurement

Time to hour

Secondary outcomes

1

Description

Determining the average length of hospital stay in the PICU

Timepoint

From the beginning of hospitalization to the time of leaving the PICU

Method of measurement

Time to hour

2

Description

Evaluation of side effect from drug use during the study period: Hypoglycemia

Timepoint

From the beginning of the acute phase of diabetic ketoacidosis until the exit of the acute phase

Method of measurement

Frequent laboratory and glucotest monitoring of blood plasma

3

Description

Evaluation of side effects due to drug use during the study period: Hypokalemia

Timepoint

From the beginning of the acute phase of diabetic ketoacidosis until the exit of the acute phase

Method of measurement

Laboratory measurement of plasma potassium levels every three hours

4

Description

Cerebral edema

Timepoint

From starting treatment for diabetic ketoacidosis to having criteria for exiting the acute phase

Method of measurement

Have any signs or symptoms of high intracranial pressure on clinical examination and vital signs according to international standards

Intervention groups

1

Description

Intervention group 1: Children who in the first 6 hours of treatment, in addition to receiving short-term standard insulin drip, receive a long dose of subcutaneous insulin effect of Detmir with a rate of 0.5 units per kilogram of child weight .

Category

Treatment - Drugs

2

Description

Control group: Standard treatment for diabetic ketoacidosis in children, including short-acting intravenous insulin, is prescribed

Category

Treatment - Drugs

3

Description

Intervention group 2: Children who in the first 6 hours of treatment, in addition to receiving standard short-term insulin drip, receive a long-acting subcutaneous insulin dose of Lantus at a rate of 0.5 units per kilogram of child weight

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Children's Hospital

Full name of responsible person

Victoria Chegini

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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research.dpt@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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 course of treatment and the main outcome of the intervention and possible complications
When the data will become available and for how long
Simultaneously with the publication of the article
To whom data/document is available
Universities of Medical Sciences
Under which criteria data/document could be used
Mention the data source in future research
From where data/document is obtainable
Qazvin Children's Hospital Hospital Research Center
Phone 0283333480
What processes are involved for a request to access data/document
Submitting a written request to the hospital research assistant
Comments