

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the effects of Normal-saline and Half-saline in the treatment of children with diabetic ketoacidosis

Protocol summary

Study aim

Comparison of time to exit from DKA, comparison of blood sugar changes, comparison of electrolyte changes, comparison of the number of patients who will have cerebral edema symptoms in the two study groups

Design

Clinical trial study, two intervention groups, parallel groups, randomized using RAS (Random Allocation Software) on 40 patients

Settings and conduct

The patients will be randomly divided into two groups using RAS software, two groups, 'Normal saline' and 'Half-saline', and homogenization will be done based on the age of the patients, and the treatment of each group will be based on the dka treatment guidelines. including compensating the lost volume and correcting acidosis and blood sugar with two different types of serum, and the treatment results of the two groups, including the time to correct acidosis, the time to correct hyperglycemia and electrolyte disturbances, the symptoms of cerebral edema, and the results of the study to choose the preferred serum more will be obtained in the treatment of dka patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with diabetic ketoacidosis Blood sugar above 200 Metabolic acidosis with ph below 7.3 Bicarbonate below 15 ketonuria No referral from other centers Exit criteria: The presence of electrolyte disorders, including serum sodium above 150 or below 130 upon arrival

Intervention groups

Patients with type 1 diabetes

Main outcome variables

Comparison of time to discharge from DKA in two groups
Comparison of blood sugar changes of patients in two groups
Comparison of electrolyte changes in two groups
Comparison of the number of patients who will have cerebral edema symptoms in two groups

General information

Reason for update

Acronym

DKA(Diabetic ketoacidosis)

IRCT registration information

IRCT registration number: **IRCT20231025059849N1**

Registration date: **2024-01-12, 1402/10/22**

Registration timing: **prospective**

Last update: **2024-01-12, 1402/10/22**

Update count: **0**

Registration date

2024-01-12, 1402/10/22

Registrant information

Name

Siamak Shiva

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3159 2105

Email address

shivas@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Normal-saline and Half-saline in the treatment of children with diabetic ketoacidosis

Public title

Comparison of the effects of Normal-saline and Half-saline in the treatment of children with diabetic ketoacidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age under 18years Blood suger above 250 Ph< 7.3
Hco3< 18 Ketonuria

Exclusion criteria:

Blood Sodium level above 150 Blood sodium level umder 130 Referral patients from other centers

Age

To **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization of flip the coin

Blinding (investigator's opinion)

Single blinded

Blinding description

Study participants will be unaware of which study group they are in. In order to prevent bias, all participants will be randomly divided into two groups, 'Normal saline' and 'Half-saline', using RAS (Random Allocation Software) software, and homogenization will be done based on the age of the patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz / Golgasht St. / Tabriz University of Medical

Sciences, Central Building No. 2 Third Floor, Research and Technology Vice-Chancellor

City

Tabriz

Province

East Azarbaijan

Postal code

5367153124

Approval date

2023-12-18, 1402/09/27

Ethics committee reference number

IR.TBZMED.REC.1402.729

Health conditions studied

1

Description of health condition studied

Diabet mellitus-DKA

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Correction of acidosis

Timepoint

In 24 hours after addmition

Method of measurement

chek of vbg every 2 hours

2

Description

Blood electrolyte changes

Timepoint

Every two hours

Method of measurement

blood test

3

Description

Blood sugar changes

Timepoint

every hour

Method of measurement

Blood sugar test

Secondary outcomes

1

Description

Brain edema symptom

Timepoint

Frequent examination every 2 hours

Method of measurement

Examining clinical symptoms including changes in level of consciousness, headache and anisocoria

Intervention groups

1

Description

Intervention group1: Group treated with normal saline serum

Category

Treatment - Drugs

2

Description

Intervention group2: Group treated with half saline serum

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mardani Azar Children's Hospital

Full name of responsible person

Dr shiva , siamak

Street address

Mardani Azar Children's Hospital, Khavaran town, Tabriz city

City

Tabriz

Province

East Azarbaijan

Postal code

5367153124

Phone

+98 41 3159 5050

Fax

+98 41 3159 5050

Email

mardaniaazar@tbzmed.ac.ir

Web page address

<https://mardaniazari.tbzmed.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

Street address

Tabriz / Golgasht St. / Tabriz University of Medical Sciences, Central Building No. 2 / Third Floor, Research and Technology Vice-Chancellor

City

Tabriz

Province

East Azarbaijan

Postal code

5367153124

Phone

+98 41 3159 5050

Email

research-vice@tbzmed.ac.ir

Web page address

<https://researchvice.tbzmed.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Shiva, Siamak

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Mardani azar Children Hospital, khavaran town,Tabriz city

City

Tabriz

Province

East Azarbaijan

Postal code

5367153124

Phone

+98 41 3159 5050

Email

Shivas@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences
Full name of responsible person
Dr shiva , siamak
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Mardani Azar Children's Hospital, Khavaran town,
Tabriz city
City
Tabriz
Province
East Azarbaijan
Postal code
5367153124
Phone
0984131595050
Email
Shivas@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr shiva , siamak
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address

Mardani Azar Children's Hospital, Khavaran town,
Tabriz city
City
Tabriz
Province
East Azarbaijan
Postal code
5367153124
Phone
0984131595050
Email
Shivas@tbzmed.ac.ir

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

Confidentiality of information

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