Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of foot reflexology massage on the breathing pattern of children with diabetic ketoacidosis

Protocol summary

Study aim
Investigating the effect of foot reflexology massage on the respiratory pattern of children hospitalized with diabetic ketoacidosis

Design
This is a randomized clinical trial with a parallel design and a control group. This randomized, non-blinded study will be conducted on 30 children with diabetic ketoacidosis. A simple random method is used for randomization and the participants are assigned to two intervention and control groups.

Settings and conduct
In this study, before starting the intervention, in order to perform the massage, first take off the jewelry, wash the hands carefully, and warm them by rubbing them together. Baby oil will be used to reduce friction

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children diagnosed with diabetic ketoacidosis Exclusion criteria: Nausea and vomiting Serum sodium level between 145-135 milliequivalent per liter

Intervention groups
In the intervention group, each foot will be massaged five times a day for fifteen minutes. A small pillow will be placed under the child's foot and the child's feet will be ready to be massaged with opening movements. Then thumb and finger techniques will be used to massage the soles and fingers. The control group will not receive any intervention.

Main outcome variables
Pattern of Breathing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N202**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **prospective**

Last update: **2023-06-18, 1402/03/28**
Update count: **0**

Registration date
2023-06-18, 1402/03/28

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-20, 1402/03/30

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of foot reflexology massage on the breathing pattern of children with diabetic ketoacidosis

Public title
Investigating the effect of foot reflexology massage on

the breathing pattern of children with diabetic ketoacidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children diagnosed with diabetic ketoacidosis

Exclusion criteria:

Nausea and vomiting Serum sodium level between 145-135 milliequivalent liters

Age

From **3 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a simple random method. Children with even file numbers will be selected as the intervention group and children with odd file numbers will be selected as the control group.

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

Islamic Azad University, Khorasgan branch

Street address

Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street

City

Isfahan

Province

Isfehan

Postal code

8155139998

Approval date

2023-04-18, 1402/01/29

Ethics committee reference number

IR.IAU.KHUISF.REC.1402.018

Health conditions studied

1

Description of health condition studied

Diabetic Ketoacidosis

ICD-10 code

E10-E14:1

ICD-10 code description

Diabetes mellitus with ketoacidosis

Primary outcomes

1

Description

Pattern of Breathing

Timepoint

The beginning of the study and the end of the study

Method of measurement

Counting the number of breaths per minute by the doctor

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, each foot will be massaged five times a day for fifteen minutes. A small pillow will be placed under the child's foot and the child's feet will be ready to be massaged with opening movements. Then thumb and finger techniques will be used to massage the soles and fingers.

Category

Treatment - Other

2

Description

The control group will not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr. Narges Sadeghi

Street address

Imam Khomeini Street, in front of Esteghlal Square, Imam Hossein Children's Educational Therapy Center

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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meshkini@miums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University, Khorasgan branch
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
Islamic Azad University, Khorasgan branch
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Member of the academic staff of Islamic Azad University, Khorasgan branch
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Person responsible for updating data

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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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