

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

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

Protocol summary

Registration timing: **prospective**

Study aim

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

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

Update count: **0**

Registration date

2023-06-18, 1402/03/28

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.

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

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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

Recruitment status

Recruitment complete

Funding source

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

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

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

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N202**

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

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	
<u>1</u>	
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	Isfahan
Postal code	8155139998
Approval date	2023-04-18, 1402/01/29
Ethics committee reference number	IR.IAU.KHUISF.REC.1402.018

Health conditions studied	
<u>1</u>	
Description of health condition studied	Diabetic Ketoacidosis
ICD-10 code	E10-E14:1
ICD-10 code description	Diabetes mellitus with ketoacidosis
Primary outcomes	
<u>1</u>	
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	
<u>1</u>	
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
<u>2</u>	
Description	The control group will not receive any intervention.
Category	N/A
Recruitment centers	
<u>1</u>	
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
City	Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University, Khorasgan branch
Full name of responsible person
Dr. Majid Meshkini
Street address
Vice Chancellor for Research Affairs, University Blvd.,
Arghwanieh, J Sharghi Street
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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
Full name of responsible person
Dr. Narges Sadeghi
Position
Member of the academic staff of Islamic Azad
University, Khorasgan branch
Latest degree
Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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