

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Investigating the effect of abdominal massage on gavage tolerance in children and adolescents under special care at Shahid Bahoner Hospital in Kerman in 2023-2024

Protocol summary

Study aim

Investigating the effect of abdominal massage on gavage tolerance in children and adolescents under special care at Shahid Bahoner Hospital in Kerman in 2023-2024

Design

This study is a two-blind phase two randomized clinical trial, the sample size is 35 people for each group (totally 70). After selecting the patients, the block randomization method with 4, 6, and 8 block sizes (with SPSS software) will be used to assign people to two groups.

Settings and conduct

This study will be conducted as a clinical trial in the special care department of Bahoner Hospital in Kerman.

Participants/Inclusion and exclusion criteria

Obtaining informed consent, children and adolescents between 8-18 years needing hospitalization in the intensive care unit, having an NG tube, - having a Glasgow coma score less than 8 (because these patients usually require gavage), intubation under mechanical ventilation for More than 3 days Exclusion criteria include: patients who were taking prokinetic drugs (due to interference with the effects of massage)

Intervention groups

A group that receives abdominal massage in addition to routine care.

Main outcome variables

Determination of gastric residual volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230723058898N1**

Registration date: **2023-12-07, 1402/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-07, 1402/09/16**

Update count: **0**

Registration date

2023-12-07, 1402/09/16

Registrant information

Name

Fateme Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3285 0177

Email address

f_ahmadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of abdominal massage on gavage tolerance in children and adolescents under special care at Shahid Bahoner Hospital in Kerman in 2023-2024

Public title

Investigating the effect of abdominal massage on gavage tolerance in children and adolescents under special care at Shahid Bahoner Hospital in Kerman in 2023-2024

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

- Obtaining informed consent Children and adolescents between 8-18 years need to be hospitalized in the intensive care unit Having an NG tube Having a Glasgow Coma Scale less than 8 (because these patients usually need gavage) Intubation under ventilation mechanical for more than 3 days

Exclusion criteria:

Patients taking prokinetic drugs (due to interference with use)

Age

From **8 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the patients, the block randomization method with 4, 6, and 8 block sizes (with SPSS software) will be used to assign people to two groups. will be. In this method, each person is assigned a unique code and it will help the blinding process. They will be placed in one of the intervention (35 patients) and control (35 patients) groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

After selecting the patients, block randomization method with 4, 6 and 8 block sizes (with SPSS software) will be used to assign people to two groups. will be. In this method, each person is assigned a unique code and it will help the blinding process.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

Street address

Kerman, the beginning of Haft Bagh Alavi axis,
University of Medical Sciences campus

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-11-10, 1402/08/19

Ethics committee reference number

IR.KMU.AH.REC.1402.063

Health conditions studied**1****Description of health condition studied**

Intolerance of gavage in children and adolescents admitted to the intensive care unit

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The amount of the remaining volume of the stomach

Timepoint

Abdominal massage is performed at 8:30 and 20:30 and the remaining volume of the stomach is measured before each gavage in two groups (the first time is considered as the zero stage and before the start of the intervention.). Therefore, the first time to determine the residual volume of the stomach in both groups is before gavage at 6 am. Then, in the model group, it is done half an hour before gavage at 9 am, and then the remaining volume of the stomach before gavage is measured with a spirae by gavage syringe three times in a similar position in all care patients, which is 30-45 degrees below the patient's head. be controlled

Method of measurement

Aspiration with a gavage syringe and pouring into a special graduated container

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: People who are subjected to an intervention (abdominal massage), then the result of that intervention is checked on the same group.

Category

Treatment - Other

2

Description

Control group: People who do not take any action and gavage is performed according to the usual method of the special care department and like the intervention group by the nursing staff of the department and 7 times a day.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital, Kerman

Full name of responsible person

Dr. Mahdi Ahmadinejad

Street address

Sepah Street, Kerman

City

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Province

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7613747181

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+98 34 3223 5011

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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mehdia50@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

50

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

Kerman University of Medical Sciences

Full name of responsible person

Dr. Mahdi Ahmadinejad

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fatema Ahmadi

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Title and more details about the data/document

The data obtained from the participants in this study will be provided to the applicants in the form of a PDF file after the completion of the study.

When the data will become available and for how long

At least six months after the start of the study

To whom data/document is available

Project facilitators and collaborators, physicians associated with the disease and poisoners and their parents

Under which criteria data/document could be used

To improve the nutrition of patients in the intensive care unit

From where data/document is obtainable

Refer to Ms. Fatemeh Ahmadi

What processes are involved for a request to access data/document

By sending a message to the respondent's email, the file will be provided to the applicant.

Comments