

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Thermotherapy on the constipation in patients admitted to intensive care units

Protocol summary

Study aim

The effect of heat therapy on constipation in ICU patients

Design

Patients will be randomly divided into intervention and control groups (30 patients in each group). The study will be single-blind and with parallel groups.

Settings and conduct

The study will be conducted in the intensive care units of Valiasr and Amir al-Momenin hospitals. The study will be one-blind. In the experimental group, local heat treatment with a temperature of 50 ° C will be performed on the abdominal surface. In the control group, in addition to routine treatments, hot packs will be used at the same time as the intervention group without warming up twice a day after the meal.

Participants/Inclusion and exclusion criteria

F) Inclusion criteria: 1. Age between 20 and 85 2. Constipation (not having bowel excretion during the last 24 hours) 3. No ulcer or injury or obvious infection in the abdomen 4. No disorders such as pancreatitis, gastrointestinal malignancies and ulcers or gastrointestinal lesions. 5. A history of gastrointestinal bleeding 6. No history of CVA and neurological diseases
Exclusion criteria: 1. Not willing to continue participating in the study 2. Discharge or death of the patient 3. Conditions that lead to fever and high body temperature above 38 ° C

Intervention groups

In the experimental group, local heat treatment with a temperature of 50 ° C will be performed on the abdominal surface. In the control group, in addition to routine treatments, hot packs will be used at the same time as the intervention group without warming up twice a day after the meal.

Main outcome variables

The impact of heat therapy on constipation in ICU patients will be assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039711N1**

Registration date: **2020-01-14, 1398/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-14, 1398/10/24**

Update count: **0**

Registration date

2020-01-14, 1398/10/24

Registrant information

Name

Mohamad Golitaleb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

Email address

m.golitaleb@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-09, 1398/10/19

Expected recruitment end date

2020-07-09, 1399/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Thermotherapy on the constipation in patients admitted to intensive care units

Public title

The effect of heat therapy on constipation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Age between 20 and 85 2. Constipation (not having bowel excretion during the past 24 hours) 3. No ulcer or injury or obvious infection in the abdomen 4. No disorders such as pancreatitis, gastrointestinal malignancies and ulcers or gastrointestinal lesions. 5. A history of gastrointestinal bleeding 6. No history of CVA and neurological diseases

Exclusion criteria:

1. Unwilling to continue studying 2. Discharge or death of the patient 3. Conditions that lead to fever and high body temperature above 38 ° C

Age

From **20 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into intervention and control groups. Sixty patients were randomly assigned to either the intervention or control groups, initially 6 blocks of 10 different T and C letters (which represent the intervention and control groups) (30) from the intervention group and 30 from the control group. People belong to the control group). Then the haba block was randomly selected to obtain a 60-sided combination of blocks. It opens to tell which group the patient falls into.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical caregivers, data analysts, and patients are not aware of being in the control or intervention group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Deputy of Education and Research, Campus University of Medical Sciences site, Basij square, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

1398.236.IR.ARAKMU.REC

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

Acute Coronary Syndrome

ICD-10 code

I20-I25

ICD-10 code description

Ischaemic heart diseases

Primary outcomes**1****Description**

Constipation

Timepoint

Before and after intervention

Method of measurement

check list

Secondary outcomes

empty

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

Intervention group: In the experimental group, topical heat treatment with a temperature of 50 ° C will be performed on the abdominal surface.

Category

Other

2**Description**

Control group: In the control group, in addition to routine treatments, hot packs will be used at the same time as the intervention group without warm-up twice a day after meals at the abdominal level.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

mohamadgolitaleb

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2

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. alireza kamali

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

mahtabfarahani

Position

nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Mohamad Golitaleb

Position

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Title and more details about the data/document

The information will be published in the final report and article.

When the data will become available and for how long

The information will be published in the final report and article.

To whom data/document is available

The information will be published in the final report and article.

Under which criteria data/document could be used

The information will be published in the final report and article.

From where data/document is obtainable

The information will be published in the final report and article.

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

The information will be published in the final report and article.

Comments

The information will be published in the final report and article.