Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 intervention 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

mohamadgolitaleb

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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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Education and Research Deputy of Arak University of Medical Sciences, Basij Square, Arak

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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
Academic instructor

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Contact

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Latest degree
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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.