# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of abdominal Thermotherapy on constipation and painful defecation in hospitalized elderly

## Protocol summary

**Study aim**
The effect of abdominal heat therapy on the improvement of constipation and pain in the elderly admitted to the internal ward

**Design**
A clinical trial with a control group, with parallel groups, randomized, on 90 patients (in two groups of 45).

**Settings and conduct**
The patients of the internal ward of Sina Arak Hospital, who having Inclusion criteria, will be randomly assigned to the intervention and control groups by the random block method, and heat therapy intervention will be performed for them. Meals will be the same for all patients (due to the privateness of the hospital, snacks will be given to patients). Blinding is not done in the study.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Cognitive health with a score higher than 7 in Abbreviated Mental Test, Hospitalization in the internal ward and having a diagnosis of constipation with the Bristol Stool Scale. exclusion criteria: having any clinical conditions that would limit the use of local heat therapy based on physician's opinion.

**Intervention groups**
For the intervention group, two times of heat therapy, 60-90 minutes after lunch and dinner, with a hot bag wrapped in a towel at a temperature of 50 Celsius, will be placed on the abdomen in the periumbilical area for 23 minutes, and in two days, a total of 4 times each patient will receive the hot water bag. For the control group, a hot bag with a 25 Celsius will be administered exactly under the same conditions as the intervention group.

**Main outcome variables**
Change in defecation and pain during defecation in hospitalized elderly patients

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170313033047N3**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **registered_while_recruiting**

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

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

**Registrant information**

**Name**
Maryam Jadid Milani

**Name of organization / entity**
Nursing Faculty of Shahed University

**Country**
Iran (Islamic Republic of)

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+98 21 6641 8589

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-06-14, 1402/03/24

**Expected recruitment end date**
2023-11-21, 1402/08/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of abdominal Thermotherapy on constipation and painful defecation in hospitalized elderly

**Public title**
The effect of abdominal Thermotherapy on constipation and painful defecation

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Over 60 years Cognitive health with a score higher than 7 in Abbreviated Mental Test(AMTs) Hospitalization in the internal department due to internal and infectious diseases based on clinical and paraclinical findings with the diagnosis of a specialist and having constipation Movement pattern of relative bed rest (RBR) according to the physician's order written in the file Having a stable physiological state to answer questions

**Exclusion criteria:**
having any clinical conditions that doubt or limit the use of local heat therapy, based on physician's order. Having alcohol and drug addiction Having psychological disorders recorded in the file Having swelling, ulcers, scratches and redness in the abdomen Having history of abdominal and pelvic surgery Having gastrointestinal diseases and ulcers (from beginning to end) Taking drugs effective on bowel movements in the last two weeks

**Age**
From **60 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **90**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Random allocation by random block method (blocks of four). Blocking is usually used in order to create a balance in the number of samples assigned to each of the studied groups. This feature helps the researchers to ensure that the number of samples allocated to each of the studied groups is equal in cases where intermediate analyzes are needed during the sampling process. The samples are assigned to intervention and control groups by blocking randomization method with blocks of 4. Block randomization is used in an online generator: "https://www.sealedenvelope.com/simple-randomiser/v1/lists". To conceal the allocation, each of the randomly created sequences is written on a card and placed in an opaque and sealed envelope. At the time of registration of the participants, based on the order of entry of the eligible participants, the envelopes will be opened in order and the assigned group of the participant will be determined.

**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**
Ethics committee of Shahed University

**Street address**
Shahed University, Persian Gulf Highway (beginning of Tehran-Qom highway), Opposite to Holy Shrine of Imam Khomeini

**City**
Tehran

**Province**
Tehran

**Postal code**
3319118651

**Approval date**
2024-02-27, 1402/12/08

**Ethics committee reference number**
IR.SHAHED.REC.1401.165

## Health conditions studied

### 1

**Description of health condition studied**
constipation

**ICD-10 code**
K59.0

**ICD-10 code description**
Constipation

## Primary outcomes

### 1

**Description**
Changing the pattern of defecation

**Timepoint**
Before the intervention, the first and second days of the intervention

**Method of measurement**
Bristol stool scale

### 2

**Description**
Change in pain during defecation

**Timepoint**
Before the intervention, the first and second days of the intervention

**Method of measurement**
Numerical scale for pain intensity measurement

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Routine intervention for constipation will be performed for all patients based on the physician's order. For the intervention group, two times of heat therapy and each time, two times of heat therapy 60-90 minutes after having lunch and evening meal (according to the hospital routine) with a hot water bag in which water is poured and then the hot water bag putting in the water for 60 to 90 Celsius and when they are heated, it is wrapped in a towel that reaches a temperature of 50 Celsius, the temperature of which is controlled by a thermometer, and the hot water bag will be placed on the abdomen, in the periumbilical area, for 23 minutes, and the intervention will take place in two days. Each patient will receive the hot water bag a total of 4 times. Meals will be the same for all patients (due to the private nature of the hospital, snacks will be given to patients and they will receive less food from outside) and have the same movement pattern.
**Category**
Treatment - Other

### 2

**Description**
Control group: For all patients, routine intervention for constipation will be performed based on physician's order. For the control group, a hot water bag with a temperature of 25 Celsius, which is determined by a thermometer, wrapped in a towel and placed on the abdomen of the patients in the periumbilical area, exactly with the schedule is similar to the intervention group. Meals will be the same for all patients (due to the private nature of the hospital, snacks will be given to patients and they will receive less food from outside) and have the same movement pattern.
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Sina Hospital, Arak city
**Full name of responsible person**
Maryam Jadid-Milani
**Street address**
The end of Hepko St., Shahidan Rajaei Blvd., next to Sadeghieh. Arak, Markazi Province, Iran.
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## Sponsors / Funding sources

### 1

**Sponsor**
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Shahed University
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Dr.Shariyar Bijani
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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**
Shahed University
**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**
Shahed University

**Full name of responsible person**
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**Position**
PhD of Nursing, assistant professor

**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)**
Undecided - It is not yet known if there will be 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**
Part of the data, such as the information related to the main outcome, can be shared.

**When the data will become available and for how long**
Access starts 6 months after the results are published

**To whom data/document is available**
It will be available only to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**
It is possible to use only the data of the main outcome of the study

**From where data/document is obtainable**
Maryam jadid-Milani Shahed University, Nursing Department milani2000ir@yahoo.com 00982151212130

**What processes are involved for a request to access**

**data/document**

The initial permission must be obtained from the research assistance of Shahid University, and then the researcher will give the requested information to the applicant.

**Comments**