

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### The effect of chewing gum on improving bowel movements in burn patients

#### Protocol summary

##### Study aim

The effect of chewing gum on improving bowel movements in burn patients

##### Design

. After diagnosis of intestinal ileus in patients hospitalized in the ward of Valiasr Hospital in Arak, by general surgery specialist, samples that have criteria for entering the research are selected and randomly (using a random number table) in one of the two experimental groups ( Chewing gum) and control. In the chewing gum group, starting from the beginning of the oral phase, chewing the chewing gum four times a day takes place for 15 minutes. The chewing gum will be free of glyceamic acid (WRIGLEY), and the control group will also receive a routine regimen. Both voice states The intestines of both groups are recorded with the use of medical examinations by a doctor who has been instructed to dispose of the dose by the nurses trained in the evaluation list. It should be noted that the examining physician and the nurse collecting information about the intervention group and the obstetrician will be unaware.

##### Settings and conduct

This study is a double-blind randomized controlled clinical trial that will be carried out in the ward Burn of Valiasr Hospital in Arak.

##### Participants/Inclusion and exclusion criteria

Entry requirements: Patients with grade 2, grade 3 or combination burns and burns more than 40% of TBSA Free of facial injuries, inhalation damage, and psychological problems, Non-arrival conditions: Patients with a history of diabetes mellitus, hypothyroidism, hypoparathyroidism, electrolyte imbalance, clear muscle and nervous diseases, and drug abuse, history of injecting drug use (anticholinergic drugs, etc.) Patients who are willing to continue studying for any reason Do not have. Not able to bear chewing gum.

##### Intervention groups

1-chewing gum 2-NPO until the onset of oral nutrition

##### Main outcome variables

Time to return the bowel sounds

#### General information

##### Reason for update

##### Acronym

The effect of chewing gum on intestinal movements in patients with burns

##### IRCT registration information

IRCT registration number: **IRCT20121230011940N4**

Registration date: **2019-05-07, 1398/02/17**

Registration timing: **prospective**

Last update: **2019-05-07, 1398/02/17**

Update count: **0**

##### Registration date

2019-05-07, 1398/02/17

##### Registrant information

##### Name

Azam Malek Hoseini

##### Name of organization / entity

Arak University of Medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1226 7892

##### Email address

m.saeedi@arak.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-09, 1398/04/18

##### Expected recruitment end date

2020-07-08, 1399/04/18

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of chewing gum on improving bowel movements in burn patients

**Public title**

The effect of chewing gum on bowel movements in burn patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The studied units have grade 2, grade 3 or combined burns and burn percentage more than 40% of TBSA. It is not more than 6 hours from the time of the burn to the time of entry into the research. According to the doctor, they need to be hospitalized. Willing to participate in research. Free of facial injuries, inhalation damage, and psychological problems.

**Exclusion criteria:**

History of diabetes, hypothyroidism, hypoparathyroidism, electrolyte imbalance, clear musculoskeletal and neurological diseases, and drug abuse. History of injecting drug use (anticholinergic drugs, etc.), for any reason, tend to continue to study. If the patient uses medications that affect the bowel movement during the interventions, people who can not tolerate chewing gum

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples that have entry criteria for research are selected and randomly (using a random number table) in one of the two test groups (chewing gum), and controlled.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The examining physician and the nurse collecting information about the intervention group and the obstetrician will be unaware.

**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**

Valiasr Hospital, Alam al-Hoda Street, Emam khomeini St, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Approval date**

2018-04-29, 1397/02/09

**Ethics committee reference number**

IR.ARAKMU.REC.1397.2

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

Burn

**ICD-10 code**

T20,T21,T2

**ICD-10 code description**

Burns

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

Time to return the bowel sounds

**Timepoint**

Every two hours once

**Method of measurement**

Hear the intestinal sounds

**Secondary outcomes****1****Description**

Gas Disposal

**Timepoint**

Every two hours once

**Method of measurement**

interview

**2****Description**

Defecation  
**Timepoint**  
Every two hours once  
**Method of measurement**  
interview

## Intervention groups

### 1

**Description**  
Intervention group: chewing gum  
**Category**  
Treatment - Other

### 2

**Description**  
Control group: Npo until the start of oral nutrition  
**Category**  
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Valiasr hospital  
**Full name of responsible person**  
Azam malek hoseini  
**Street address**  
Ayatollah Ghafari St., Vali Asr (aj)  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3817834467  
**Phone**  
+98 86 3226 7892  
**Email**  
malekhoseni.aram@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Azam malekhoseini  
**Street address**  
Ayatollah Ghafari St., Vali Asr (aj)  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
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**Phone**

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**Email**  
malekhoseni.aram@gmail.com

**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**  
Azam malekhoseini  
**Position**  
Academic staff  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Ayatollah Ghafari St., Vali Asr (aj)  
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**Postal code**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Azam malek hoseini  
**Position**  
Academic staff  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Azam malekhoseini

**Position**

Academic staff

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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**Province**

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**Postal code**

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**Email**

malekhoseni.aram@gmail.com

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available