

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the effect of chewing gum and common method on the improvement of intestinal movements in burn patients

Protocol summary

Study aim

Determine the effect of chewing gum on improving bowel movements in burn patients

Design

A clinical trial with a control group, community-based and pragmatic, with parallel, randomized groups

Settings and conduct

This study is a double blind randomized clinical trial. After diagnosis of intestinal ileus in patients hospitalized in the burn ward of Vali-e-Asr Hospital in Arak

Participants/Inclusion and exclusion criteria

Entry requirements: Degree 2, Grade 3 or Combined with Burn% more than 40% 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. Non-arrival conditions: History of diabetes, hypothyroidism, hypoparathyroidism, electrolyte imbalance, clear musculoskeletal and neurological diseases, and drug abuse. Taking active medications for the gut (anticholinergic drugs, etc.) Unwillingness to continue participating in the study Gum intolerance

Intervention groups

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 assigned to one of the two experimental groups (chewing gum) and controlled. In the chewing gum group, starting from the beginning of the oral phase, chewing the chewing gum four times a day is carried out for 15 minutes. Dosages given without Gem Baccarat Fife (WRIGLEY Company) will be initiated, and the control group will begin the fasting oral nutrition from the start.

Main outcome variables

The onset of bowel sounds, the onset of first gas excrement, first fecal excretion, the onset of a diet Time out of bed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180715040478N1**

Registration date: **2021-07-27, 1400/05/05**

Registration timing: **retrospective**

Last update: **2021-07-27, 1400/05/05**

Update count: **0**

Registration date

2021-07-27, 1400/05/05

Registrant information

Name

Azam Malekhoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

Azam.malekhoseini@khomeinums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-22, 1397/04/31

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of chewing gum and common method on the improvement of intestinal movements in burn patients

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with grade 2, grade 3 or combined burns
Patients with a burn rate greater than 40% TBSA Willing to participate in research. Free of facial injuries, inhalation injuries and psychological problems.

Exclusion criteria:

History of diabetes, hypothyroidism, hypoparathyroidism, electrolyte imbalance, clear muscle and nervous diseases, drug abuse. History of drug use (anticholinergic drugs and ...) For any reason, they tend to continue to participate in the study. If the patient uses medications that affect bowel motility The patient declining to take part in research;

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

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 Arak University of Medical Sciences

Street address

Shahid Shiroodi Street

City

Arak

Province

Markazi

Postal code

3819693345

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

T30.3

ICD-10 code description

T30.2

Primary outcomes

1

Description

bowel movements

Timepoint

Every two hours once

Method of measurement

Listening to intestinal sounds - Ask about gas or feces

Secondary outcomes

1

Description

Intestinal sounds

Timepoint

Every two hours once

Method of measurement

Listening to intestinal sounds - Ask about gas or feces

Intervention groups

1

Description

Intervention group: chewing gum

Category

Treatment - Other

2

Description

Control group: Routine diet

Category

Treatment - Other

Recruitment centers

empty

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Azam Malekhoseni

Street address

Floor 3; Bldg Emam Mosaa Kazem; University of Medical Sciences Complex; Sq Basij; Sardasht

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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

Azam Malekhoseini

Position

Coach

Latest degree

Master

Other areas of specialty/work

Nursery

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Latest degree

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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

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