

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
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3817834467
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+98 86 3226 7892
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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)
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Province
Markazi
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3817834467
Phone

+98 61 3226 7892
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

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

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Full name of responsible person

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Position

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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