Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 86 3417 3505

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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 mo 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
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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