Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 glycemic 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)
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+98 86 1226 7892
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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

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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

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Markazi

Postal code

3817834467

Phone

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Email

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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

Academic staff

Latest degree

Master

Other areas of specialty/work

Nursery

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Other areas of specialty/work

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Person responsible for updating data

Contact
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Full name of responsible person
Azam malekhoseini
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