

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The Effect of Dimethicon On Prevention Of Ileus In Patients Suffering From Pelvic and Femoral Fractures A Randomized Clinical Trial

Protocol summary

Study aim

Determination of ileus incidence in patients with pelvic fracture and femur who received demthicone. The incidence of ileus in patients in the control group
Comparison of ileus incidence in intervention and control groups.

Design

After obtaining written consent, the available samples will be randomly divided into two groups of intervention and control using random 4 percentiles. Allocation: Random Based on the lack of similar studies and lack of sufficient information to calculate the sample size, according to experts, the probability of ileus incidence in patients (control group) and in the permanent group was 25%. By taking $\alpha=5\%$ The sample size in each group was 55 samples.

Settings and conduct

The study is performed on patients with pelvic and femoral fractures in Madani Hospital. The study will be performed by giving 40 mg dimethicone tablets 3 times a day to the intervention group and observation of the control group. The duration of follow-up is from hospitalization to discharge. Then, the effect of dimethicone on prevention of ileus and the frequency of ileus in the control group and Intervention is investigated. Finally, the data obtained from the patients will be collected in a questionnaire and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with different types of pelvic and femoral fractures who were admitted to Madani Hospital for at least 3 days and treated during the study. Exclusion criteria: Patients will be excluded if they have symptoms of ileus or take prokinetic drugs before surgery.

Intervention groups

Intervention group: Patients with pelvic and femoral fractures who will be used to prevent ileus dimethicone.
Control group: Patients with pelvic and femoral fractures who will undergo routine treatment without receiving any

specific medications.

Main outcome variables

Incidence of Ileus in Observation and Intervention Group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200708048064N1**

Registration date: **2020-11-23, 1399/09/03**

Registration timing: **prospective**

Last update: **2020-11-23, 1399/09/03**

Update count: **0**

Registration date

2020-11-23, 1399/09/03

Registrant information

Name

Shayan Shahsavary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3448 4802

Email address

shadesofshayan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-30, 1399/09/10

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Dimethicon On Prevention Of Ileus In Patients Suffering From Pelvic and Femoral Fractures A Randomized Clinical Trial

Public title
The Effect of Dimethicon On Prevention Of Ileus In Patients Suffering From Pelvic and Femoral Fractures A Randomized Clinical Trial

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: All patients with different types of pelvic and femoral fractures who were admitted to Madani Hospital for at least 3 days and treated during the study.
Exclusion criteria:
Exclusion criteria: Patients will be excluded if they have symptoms of ileus or take prokinetic drugs before surgery.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization will be used. Each block will contain 4 individuals. The sequence of patients in each block is random. The number of subjects is equal and two are from the intervention group and two are from the control group. Stratification of Randomization will not be used.

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 Alborz University of Medical Sciences

Street address

Research and Technology Committee - Saffari Ave , 45 meter Golshahr Street , Karaj

City

کرج

Province

Alborz

Postal code

3198764653

Approval date

2020-10-10, 1399/07/19

Ethics committee reference number

IR.ABZUMS.REC.1399.188

Health conditions studied

1

Description of health condition studied

Ileus In Hip and femoral fracture Patients

ICD-10 code

K56.0

ICD-10 code description

Paralytic ileus

Primary outcomes

1

Description

Determining Incidence rate of Ileus in patients receiving dimethicone

Timepoint

From the onset of admission in ward

Method of measurement

Patient History - Clinical Examination

Secondary outcomes

1

Description

Comparison of gas passage time between intervention and control groups

Timepoint

From hospitalization until gas passage during hospitalization

Method of measurement

Patient history

Intervention groups

1

Description

Intervention group: Dimethicone 40 mg Pills will be given to the Intervention group three times a day and it will be consumed from the point of admission in hospital. So far, no study has been conducted to investigate the effect of

dimethicone to prevent ileus following pelvic and femoral fractures. The closest study was to investigate the effect of simethicone on ileus after colorectal surgery.(1) In some cases, acupuncture and simo decoction, alvimopan and chewing gum, in studies have been useful in the treatment of ileus.(2 , 3 , 4) Despite several studies on the factors affecting the incidence of ileus and the study of different treatments, a suitable preventive method has not yet been suggested to prevent this complication, which indicates the necessity of further and wider studies in this case, so due to the high prevalence of ileus in patients of Madani hospital, it was decided to investigate a method to prevent this disease.

References: (1)Jeremy E.Springer ShirazElkheir CaglaEskicioglu Aristithes G.Doumouras StephenKelly llunYangaShawnForbes. The effect of simethicone on postoperative ileus in patients undergoing colorectal surgery(SPOT), a randomized controlled trial. International Journal of Surgery Volume 56, August 2018, Pages141-147) (2 Wolff BG, Michelassi F, Gerkin TM, Techner L, Gabriel K, Du W, et al. Alvimopan, a Novel, Peripherally .1Acting μ Opioid Antagonist: Results of a Multicenter, Randomized, Double-Blind, Placebo-Controlled, PhaseIII Trial of Major Abdominal Surgery and Postoperative Ileus. Annals of surgery. 2004;240(4):728-35.) (3 Yang Y, Zuo HQ, Li Z, Qin YZ, Mo XW, Huang MW, et al. Comparison of efficacy of simo decoction and acupuncture or chewing gum alone on postoperative ileus in colorectal cancer resection: a randomized trial.Scientific reports. 2017;7:37826.) (4 van den Heijkant TC, Costes LM, van der Lee DG, Aerts B, Osinga-de Jong M, Rutten HR, et al.Randomized clinical trial of the effect of gum chewing on postoperative ileus and inflammation in colorectal surgery. The British journal of surgery. 2015;102(3):202-11.)

Category

Prevention

2

Description

Control group:The Control Group will be Treated with Routine Care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Madani Hospital of Karaj

Full name of responsible person

Haleh paak

Street address

Shahid Madani Square , Jahanshar , karaj

City

karaj

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Alborz

Postal code

3155718631

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halehpak80.md@gmail.com

Web page address

https://madani.abzums.ac.ir/fa-IR/madani.abzums.ac/8115/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Haleh paak

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3155718631

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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

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Haleh paak

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Shayan Shahsavary

Position

Intern

Latest degree

Medical doctor

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