Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 a=%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 comittee 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: (1Jeremy E.Springer ShirazElkheir CaglaEskicioglu Aristithes G.Doumouras StephenKelly IlunYangaShawnForbes. 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

Province
Alborz

Postal code
3155718631

Phone
+98 26 3250 8967

Fax
+98 26 3442 6979

Email
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

Street address
Shahid madani Square , Jahanshar , Karaj

City
Karaj

Province
Alborz

Postal code
3155718631

Phone
+98 26 3250 8967

Email
halehpak80.md@gmail.com

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
Street address
Shahid madani Square, Jahanshar , Karaj
City
Karaj
Province
Alborz
Postal code
3155718631
Phone
+98 26 3250 8967
Email
halehpak80.md@gmail.com

Person responsible for scientific 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
Street address
Shahid madani Square, Jahanshar , Karaj
City
Karaj
Province
Alborz
Postal code
3155718631
Phone
+98 26 3250 8967
Email
halehpak80.md@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Shayan Shahsavary
Position
Intern
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
2nd unit , No.58 , Ninth avenue , Kasra Street , Jahanshahr , Karaj
City
Karaj
Province
Alborz
Postal code
3144963135
Phone
+98 26 3448 4802
Fax
Email
shadesofshayan@gmail.com

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