Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of oral pyridostigmine on ileus after abdominal surgery

Protocol summary

Study aim
To evaluate the effect of oral pyridostigmine on ileus after abdominal surgery

Design
A single-blind clinical trial with a control group to determine randomized effect of the treatment

Settings and conduct
This study was performed in three sections of general surgery in Zahedan University of Medical Sciences. To this end, 40 patients were selected and divided into two groups of 20 patients each. A parallel intervention was daily conducted in both groups by the researcher's colleague and the patients were not aware of the type of group they were in.

Participants/Inclusion and exclusion criteria
The inclusion criteria were having ileus for more than 3 days and the consent to participate in the study. The exclusion criteria were heart rate less than 60 times per minute, blood pressure less than 90 mmHg, age below 18 years, finding mechanical causes for inactivity of the intestines, heart problem, colon cancer and small bowel cancer.

Intervention groups
Group One: (20 patients) Patients received oral pyridostigmine at a dose of 60 mg twice daily via NG TUBE. Group two: (20 patients) the control group received starch twice daily via NG TUBE.

Main outcome variables
Treatment effect time: treatment effect frequency

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180123038484N1**
Registration date: **2018-02-17, 1396/11/28**
Registration timing: **retrospective**
Last update: **2018-02-17, 1396/11/28**
Update count: **0**

Registration date
2018-02-17, 1396/11/28

Registrant information

Name
Abdobaset Malek Raeisi Nejad

Name of organization / entity

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Iran (Islamic Republic of)

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+98 54 3522 3101

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a.malek@zaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-01-21, 1393/11/01

Expected recruitment end date
2015-03-21, 1394/01/01

Actual recruitment start date
2015-01-21, 1393/11/01

Actual recruitment end date
2015-05-22, 1394/03/01

Trial completion date
empty

Scientific title
Evaluation of the effect of oral pyridostigmine on ileus after abdominal surgery

Public title
the effect of oral pyridostigmine on ileus after abdominal surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

having ileus for more than 3 days the consent to participate in the study

Exclusion criteria:

heart rate less than 60 times per minute blood pressure less than 90 mmHg age below 18 years finding mechanical causes for inactivity of the intestines heart problem colon cancer and small bowel cancer

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

randomized block sampling

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants: That is, patients are aware of being involved in the study, but not aware of which group they are in at the time of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan university of medical sciences

Street address

Zahedan University of Medical Sciences, Dr Hesabi sq, Zahedan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9993134567

Approval date

2014-05-12, 1393/02/22

Ethics committee reference number

IR.ZAUMS.REC.1393.966

Health conditions studied

1

Description of health condition studied

postoperative ileus (poi)

ICD-10 code

K91.89

ICD-10 code description

Other postprocedural complications and disorders of digestive system

Primary outcomes

1

Description

Time for effectiveness

Timepoint

each hour

Method of measurement

Researcher-made questioner

2

Description

frequency of effectiveness

Timepoint

each hour

Method of measurement

Researcher-made questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: (20 patients) Patients received oral pyridostigmine at a dose of 60 mg twice daily via NG TUBE.

Category

Treatment - Drugs

2

Description

Control group: (20 patients) the control group received starch twice daily via NG TUBE.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali hospital

Full name of responsible person
Alireza Khazaei
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Zahedan University of Medical Sciences, Dr Hesabi sq, Zahedan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
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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
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Abdobaset Malek Raeisi Nejad
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Some part of data
When the data will become available and for how long
Start of access to data from six months after publishing the paper.
To whom data/document is available
Universities
Under which criteria data/document could be used
for more analysis only for some parts.
From where data/document is obtainable
PI Email: a.malek@zaums.ac.ir
What processes are involved for a request to access data/document
Send email to PI in Email: a.malek@zaums.ac.ir
Comments