

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

Country

Iran (Islamic Republic of)

Phone

+98 54 3522 3101

Email address

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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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

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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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Person responsible for updating data**Contact****Name of organization / entity**

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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