

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Use high dose of intrathecal sufentanil for intraoperative and postoperative pain relife in gastrointestinal cancers surgeries

Protocol summary

Study aim

Effective and better control of patients pain during and after surgery

Design

Clinical trial with control group with parallel groups, one side blinding, with blinded outcome assessment, randomized, phase 3 on 50 patients.

Settings and conduct

Adult aged between 18 and 75 years old who have referred to Imam Reza and Ghaem hospital in Mashhad for gastrointestinal cancer surgeries were selected on the condition of non addiction and no history of drug allergy. After obtaining informed consent , they will be devided into two groups of control and intervention by blocked randomization method.At the end of the sampling, the data will be given to the data analyzer whom have been kept blind in assigning individuals to study groups for analysis.

Participants/Inclusion and exclusion criteria

Adults between 18 and 75 years No addiction Personal consent to participate in the project No history of allergies to sufentanil and other drugs

Intervention groups

In the intervention group, immediately before induction of anesthesia, intrathecally received 0.2 micrograms per kilogram of weight of sufentanil(Caspian or Abureihan)and did not receive intravenous opioids during induction of anesthesia. In the control group intravenously during induction of anaesthesia received 0.3 micrograms per kilogram of weight intravenous sufentanil and the need for drug repetition during and after surgery in these patients was assessed in a similar way.

Main outcome variables

pain relief and non-repeated use of intravenous opioid drugs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210129050174N1**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

Registration date

2021-12-20, 1400/09/29

Registrant information

Name

Naser Naderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3601 9567

Email address

naderin971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Use high dose of intrathecal sufentanil for intraoperative and postoperative pain relief in gastrointestinal cancers surgeries

Public title

The effect of intrathecal sufentanil on analgesia of gastrointestinal cancer surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults who are between 18-75 years old Informed consent for participation in project Candidate for gastrointestinal cancers surgeries

Exclusion criteria:

No addiction No history of allergy to sufentanil or other drugs

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyst

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

People who are going to enter the study, are divided into ten groups of five by blocked randomization method. The first group of five is assigned to the intervention or control group by heads or tails method. The next five person groups will be placed in the intervention or control group alternately according to the first group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyzer are kept blind to assignment to study groups and information is provided to them at the end of the project for analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

No 111, Jalal Al Ahmad 10, Jalal Al Ahmad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9188875791

Approval date

2020-11-18, 1399/08/28

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.580

Health conditions studied

1

Description of health condition studied

Pain relief in gastrointestinal cancers surgeries

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Pain score in pain numerical scale

Timepoint

At the beginning of surgery and every twenty minutes until the end of surgery

Method of measurement

Pain numerical scale

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, immediately before induction of anesthesia, intrathecally received 0.2 micrograms per kilogram of weight of sufentanil (Caspian or Aburihan) and did not receive intravenous opioids during induction of anesthesia. During surgery with due attention to vital signs (20% increase in systolic blood pressure or heart rate compared to baseline values) and also after surgery by monitoring the patient in terms of expressing the first complaint of pain according to the pain scale Numerical and achieving score 3 In the pain table (according to the attached checklist) the need for re-administration of analgesic drug was assessed.

Category

Treatment - Drugs

2

Description

Control group: They receive 0.3 micrograms per kilogram of intravenous sufentanil weight.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

Seyyed Alireza Bameshki

Street address

Imam reza hospita square, Imam Reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3858 3878

Email

IRH@mums.ac.ir

Web page address

2

Recruitment center

Name of recruitment center

Graem hospital

Full name of responsible person

Alireza Bameshki

Street address

Ahmadabad Blvd, Shariati square

City

Mashhad

Province

Razavi Khorasan

Postal code

9187145788

Phone

+98 51 3840 0001

Email

b.ghaem@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Deputy of Research and Technology,Ghoreshi building, building,Daneshgah Ave.,

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

vcresraech@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Seyyed Alireza Bameshki

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department Office, 610 building,Imam Reza hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

0098513858387

Email

bameshkiar@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyyed Alireza Bameshki

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department Office,610 building,Imam Reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3858 3878

Email

bameshkiar@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Naser Naderi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

No 111, Jalal al ahmad 10 Ave, Jalal al ahmad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9188875791

Phone

+98 51 3601 9567

Fax

Email

naderin971@mums.ac.ir

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

The main outcome of the study is shared.

When the data will become available and for how long

Access starts from Mehr 1401

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use the data for further studies

From where data/document is obtainable

Dr. Seyyed Alireza Bamshki - Anesthesiology Department of Imam Rez Hospital

What processes are involved for a request to access data/document

Submit a request via email to Dr. Seyyed Alireza Bamshki bameshkiar@mums.ac.ir

Comments