

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparing the effect of fentanyl in addition to oxygen therapy on pain in patients undergoing bone marrow aspiration and biopsy

#### Protocol summary

##### Study aim

The aim of this study was to compare the effect of fentanyl with and without oxygen therapy and placebo on pain in patients undergoing aspiration and bone marrow biopsy.

##### Design

In randomized, double-blinded, controlled clinical trial, phase 3, 60 patients, who are referred for bone marrow aspiration and biopsy, are randomly divided into three groups including: intervention groups A and B, and control group.

##### Settings and conduct

This study is conducted at Kowsar Hospital, an academic hospital affiliated with the Semnan University of Medical Sciences and Health Services. In this clinical trial, patients are randomly assigned to three groups and interventions are conducted. Intervention group A receive 2 mL fentanyl intravenously, intervention group B receive 2 mL fentanyl intravenously in addition to oxygen, before and during the procedure. The control group (C) receive oxygen for 30 minutes before and during the procedure. Person who evaluated outcomes and patients are not aware from the type of intervention.

##### Participants/Inclusion and exclusion criteria

Study population include patients who are referred for bone marrow aspiration and biopsy. All patients older than 18 years old and who have complete awareness enrolled in study. Patients who use narcotics and analgesic, need to oxygen therapy, those who have pacemaker and pregnant women are excluded from study.

##### Intervention groups

Intervention group A receive 2 mL fentanyl intravenously after local anesthesia. Intervention group B receive 2 mL fentanyl intravenously after local anesthesia in addition to oxygen, 8 liters per minute through face mask for 30 minutes before and during the diagnostic procedure. The control group (C) receive oxygen through face mask for 30 minutes before and during the procedure.

#### Main outcome variables

The main outcome is pain in the site of biopsy.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151020024625N9**

Registration date: **2018-09-14, 1397/06/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-14, 1397/06/23**

Update count: **0**

##### Registration date

2018-09-14, 1397/06/23

##### Registrant information

##### Name

Mehrdad Zahmatkesh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3343 7844

##### Email address

mehrdadzahmatkesh@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-04, 1397/01/15

##### Expected recruitment end date

2019-02-03, 1397/11/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effect of fentanyl in addition to oxygen therapy on pain in patients undergoing bone marrow aspiration and biopsy

**Public title**

Effect of fentanyl in addition to oxygen therapy in relieving pain

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age older 18 years Complete consciousness

**Exclusion criteria:**

Pregnancy Pacemaker Any diseases that need to oxygen therapy

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are randomly allocated in two groups by using of random number block. Random numbers can be generated by computer. The first block is allocated to intervention group A, second block is allocated to intervention group B and third block is allocated to control group and this process continues until the last block.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patient and care provider don't aware from intervention.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Semnan University of Medical

Sciences

**Street address**

Basidj Boulevard

**City**

Semnan

**Province**

Semnan

**Postal code**

3519899951

**Approval date**

2018-02-06, 1396/11/17

**Ethics committee reference number**

IR.SEMUMS.REC.1396.226

**Health conditions studied****1****Description of health condition studied**

Pain

**ICD-10 code**

R52.9

**ICD-10 code description**

Pain, unspecified

**Primary outcomes****1****Description**

Pain Relief

**Timepoint**

After Intervention

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention Group A receive 2 mL fentanyl intravenously after local anesthesia

**Category**

Treatment - Drugs

**2****Description**

Intervention Group B receives 8 liters per minute of oxygen through face mask for 30 minutes before and during the procedure, in addition to fentanyl 2 mL intravenously.

**Category**

Treatment - Drugs

### 3

#### Description

Control group only receive oxygen through face mask for 30 minutes before and during the procedure:

#### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Kowsar Hospital, Semnan

###### Full name of responsible person

Farahnaz ghahremanfard

###### Street address

Basidj Boulevard

###### City

Semnan

###### Province

Semnan

###### Postal code

3519899951

###### Phone

+98 23 3142 2120

###### Email

f\_ghahremanfard@yahoo.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Semnan University of Medical Sciences

###### Full name of responsible person

Parviz Kokhaei PhD

###### Street address

Basidj Boulevard

###### City

Semnan

###### Province

Semnan

###### Postal code

3519899951

###### Phone

+98 23 3345 1336

###### Email

p\_kokha@yahoo.com

###### Grant name

###### Grant code / Reference number

###### Is the source of funding the same sponsor organization/entity?

Yes

###### Title of funding source

Semnan 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

Semnan University of Medical Sciences

##### Full name of responsible person

Mehrdad Zahmatkesh

##### Position

Research Expert

##### Latest degree

Bachelor

##### Other areas of specialty/work

Biostatistics

##### Street address

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mehrdadzahmatkesh@semums.ac.ir

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Semnan University of Medical Sciences

##### Full name of responsible person

Farahnaz Ghahremanfard MD

##### Position

Associate Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Hematology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Mehrdad Zahmatkesh

**Position**

Research Expert

**Latest degree**

Bachelor

**Other areas of specialty/work**

Biostatistics

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Semnan

**Postal code**

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+98 23 3142 2252

**Email**

mehrdadzahmatkesh@semums.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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Final report will published after completing of study.

**When the data will become available and for how long**

After publishing of results.

**To whom data/document is available**

Researcher and others for similar studies.

**Under which criteria data/document could be used**

Researchers and specialists

**From where data/document is obtainable**

by email.

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

Providing of scientific ID.

**Comments**