

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Comparison of the effect of morphine and oxycodone in relieving pain in patients with bone metastasis pain

#### Protocol summary

##### Study aim

The effect of morphine with oxycodone in relieving pain in patients is compared with pain due to bone metastases

##### Design

Randomized clinical trial, with parallel groups, double-blind, phase 3 on 32 patients, block method and online software [www.sealedenvelope.com](http://www.sealedenvelope.com) were used for randomization.

##### Settings and conduct

This study is a double-blind randomized clinical trial in Khansari Hospital in Arak in 1399 with easy sampling. All patients who are candidates for analgesia and have inclusion criteria will be evaluated as the study population after completing the informed consent form. In this study, 32 patients are divided into two completely equal groups using morphine and oxycodone using block randomization. Due to the two-sided blindness of the study, in this study, only specialists The person in charge of the study is aware of the type of study and the study groups, while patients are not aware of the type of prescription drug. It is not aware and only recognizes groups based on A and B and fills checklists accordingly.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with malignancy with bone metastasis confirmed by bone scan Candidate for analgesia, was less than 6. Exclusion criteria: history of diabetes and kidney failure, bone fracture, hypotension, bradypnea

##### Intervention groups

In the first intervention group, 16 patients received 5 mg morphine intravenously and placebo tablets only once at the beginning of the intervention and in the second intervention group, 16 patients took two 5 mg oxycodone tablets orally, together and by injection alone. Once received at the beginning of the intervention.

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201202049575N1**

Registration date: **2020-12-09, 1399/09/19**

Registration timing: **prospective**

Last update: **2020-12-09, 1399/09/19**

Update count: **0**

##### Registration date

2020-12-09, 1399/09/19

##### Registrant information

##### Name

Mahdi Farahani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3505

##### Email address

m.mahdi.f.13732324@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2021-01-20, 1399/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of morphine and oxycodone in relieving pain in patients with bone metastasis pain

**Public title**

The effect of morphine and oxycodone on bone metastatic pain

**Purpose**

Supportive

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

All patients with malignancy whose bone metastasis has been confirmed by bone scan and are candidates for analgesia. Pain intensity less than 6 based on vas ruler

**Exclusion criteria:**

Have low blood pressure, Bradypnea Have a bone fractures History of diabetes and kidney failure

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **32**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using block randomization method and online statistical software ([www.sealedenvelope.com](http://www.sealedenvelope.com)), 32 patients will be divided into two equal groups of intervention and control in 8 blocks of 4. To hide random sequences, the sealed envelope method is used. First, a random sequence is created by one of the mentioned methods. , Are prepared and each of the random sequences created is recorded on a card and the cards are placed in the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes is opened in order and the assigned group of the participant is revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Due to the double-blindness of the study, blindness is such that only the relevant specialist in charge is aware of the type of the study and groups , while patients are not aware of the type of prescription drug and blind using injectable and oral placebo. Also, the clinical caregivers and interns in charge of the project, who are in charge of filling out the checklists, are not aware of the type of groups based on the prescription drug and only recognize the groups based on A and B and check the checklists.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

thics committee of Arak University of Medical Sciences

**Street address**

Payambar-e-azam Complex, Basij Sq., Sardasht

**City**

Arak

**Province**

Markazi

**Postal code**

3848176341

**Approval date**

2020-11-08, 1399/08/18

**Ethics committee reference number**

IR.ARAKMU.REC.1399.230

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

Bone metastasis

**ICD-10 code**

C41

**ICD-10 code description**

Malignant neoplasm of bone and articular cartilage of other and unspecified sites

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

Pain

**Timepoint**

Before the intervention, 30 minutes, 2 hours and 6 hours after the intervention

**Method of measurement**

visual analogue scale for pain

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

First intervention group: In the first group, 16 patients received morphine sulfate (Darupakhsh-Iran) 5 mg intravenously once at the beginning of the intervention and two placebo tablets orally once at the beginning of the intervention.

### Category

Treatment - Drugs

## 2

### Description

Second intervention group: In the second group, 16 patients receive two 5 mg oxycodone tablets (Shafa-Iran) orally and simultaneously, and only once at the beginning of the intervention and an injectable placebo of 5 ml, once at the beginning of the intervention.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Valiasr hospital

##### Full name of responsible person

Mahdi Farahani

##### Street address

Valiasr sq.

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Email

pr\_valieasr@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Alireza Kamali

##### Street address

Payambar-e-azam Complex, Basij Sq., Sardasht

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3848176341

##### Phone

+98 86 3417 3639

##### Email

research@arakmu.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Mahdi Farahani

##### Position

Student

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

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## Person responsible for scientific inquiries

#### Contact

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

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**Full name of responsible person**

Mahdi Farahani

**Position**

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**Latest degree**

A Level or less

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**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