

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation of topical moxifloxacin effectiveness and placebo in general Surgeries wound healing

#### Protocol summary

##### Study aim

Therapeutic Comparison of wound healing rate in two groups of topical moxifloxacin and placebo

##### Design

Control-controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 80 patients used the Excel software rand function for randomization

##### Settings and conduct

This project will take place at Shahid Sadoughi Hospital in Yazd. Patients in two groups of 40 people use moxifloxacin cream twice a day for 5 days

##### Participants/Inclusion and exclusion criteria

Diabetes renal failure Liver failure Epilepsy Rheumatoid Arthritis Heart failure

##### Intervention groups

In order to evaluate the effectiveness of moxifloxacin cream in wound healing at the surgical site, we give a group of 40 people with moxifloxacin and a group of 40 people with a placebo.

##### Main outcome variables

Age Sex Redness Edema Ecchymosis Discharge Approximation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181208041882N5**

Registration date: **2021-10-25, 1400/08/03**

Registration timing: **prospective**

Last update: **2021-10-25, 1400/08/03**

Update count: **0**

##### Registration date

2021-10-25, 1400/08/03

##### Registrant information

##### Name

behrooz heydari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 8699

##### Email address

b.heydari@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-06, 1400/08/15

##### Expected recruitment end date

2021-11-11, 1400/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of topical moxifloxacin effectiveness and placebo in general Surgeries wound healing

##### Public title

Evaluation of moxifloxacin effectiveness in wound healing

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients who have undergone general surgery Patients over 18 years old

##### Exclusion criteria:

Diabetes Liver failure Renal failure Epilepsy Rheumatoid Arthritis Heart failure

##### Age

From **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this study, 80 patients were randomly divided into two treatment groups (A and B). In order to randomize, the block random allocation method was used, in which 10 blocks of 8 were considered. The letters A and B. These permutations were generated with the help of Random software distribution software version 1. For this purpose, the list prepared by software No. 1 to 80 is in 10 blocks of eight in general to implement this I want the software output to the first eligible person number 1 and I want to select the last person number 80.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study patients, clinical caregivers and outcome assessors were unaware of the type of medication patients were receiving. Patients in both groups received the medication in the same package. After randomization of the questionnaires, the statistics consultant was provided, and she divided the patients into two groups of 40 based on the numbers written in the questionnaire and using a table of random numbers. To blinding the drug tubes with the same appearance, which deprives the researcher and patients of identifying the drug from Placebo, it was prepared by a clinical pharmacologist and provided to the researcher.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

###### Street address

Shahid Sadoughi University of Medical

Science,Shohadaye Gomnam Blvd,Alem Sq

#### City

Yazd

#### Province

Yazd

#### Postal code

8915173143

#### Approval date

2019-05-19, 1398/02/29

#### Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.080

### Health conditions studied

#### 1

##### Description of health condition studied

Wounds from the site of general surgery

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

Review of the Redness, Edema, Ecchymosis, Discharge, Approximation index

##### Timepoint

Days 0, 1, 3 and 5 after surgery

##### Method of measurement

Observational

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Patients use moxifloxacin cream on the suture site for 5 days after surgery. In this study, 80 patients were randomized into two treatment groups (A and B). In both groups, the topical product was used on the wound three times per day. All patients were taught non-pharmacological procedures such as washing, proper wound dressing, and how to care for the wound. The two groups were not different in terms of non-pharmacological measures.

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: Patients use placebo cream on the suture site for 5 days after surgery

##### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid sadoughi hospital

**Full name of responsible person**

Saeed kargar

**Street address**

Ibn Sina Street, Shahid Ghandi Boulevard, Safaieh

**City**

Yazd

**Province**

Yazd

**Postal code**

۸۹۱۵۸۸۷۸۵۷

**Phone**

+98 35 3822 4000

**Email**

sadoughi-hospital@ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Masoud Mirzaei

**Street address**

Shahid sadoughi university of medical science,shohadaye Gomnam Blvd,Alem Sq

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Yazd

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+98 35 3820 3410

**Email**

b.heydari@ssu.ac.ir

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

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Behrooz heydari

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

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Assistant professor

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Ph.D.

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## Person responsible for updating data

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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**

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**

After nonrecognition, all data can be share

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

6 months after publication

**To whom data/document is available**

All of researchers

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

nothing

**From where data/document is obtainable**

Behrooz Heydari email: b.heydari@ssu.ac.ir

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

Request your information by email. The data will be sent after a week.

**Comments**