

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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)

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+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 Gornam 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

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Postal code

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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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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

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Person responsible for scientific inquiries

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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