

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of open wound management via vacuum dressing with and without fibrinolysin

Protocol summary

Study aim

a) the role of Fibrinolysin in open wound management via using a vacuum dressing in Imam Khomeini Hospital Tehran 2022-2023 b) benefits of using Fibrinolysin in open wound management through using a vacuum dressing in Imam Khomeini Hospital Tehran 2022-2023 c) time for wound healing with and without Fibrinolysin upon the surface area of wounds through using a vacuum dressing in Imam Khomeini Hospital Tehran 2022-2023 d) comorbidities by using Fibrinolysin in open wound management through using a vacuum dressing in Imam Khomeini Hospital Tehran 2022-2023 e) complications in using Fibrinolysin in open wound management through using a vacuum dressing in Imam Khomeini Hospital Tehran 2022-2023

Design

Fibrinolysin Intervention group, non-fibrinolysin control group, sample size 22, Randomised Control Trial, single-center, enrolled in the year 2022

Settings and conduct

The blocking method is used for randomization and the numbering and tagging of blocks will be four. Blinding will be performed on patients and they will not be aware that they are in the intervention or control group. In addition, the selection of patients in each group will be available by the method.

Participants/Inclusion and exclusion criteria

This study includes all patients with the same type and of similar size of the open wound which will be managed via Vacuum Dressing admitted in the imam Khomeini hospital, Tehran, Iran from 2022 to 2023.

Intervention groups

1 Topical Ointment Westagen Pars Fibrinolysin 20g per patient Used for 24 Hours 1 session It cleans dead tissues from wounds and causes the dilution of pus and dissolution of blood clots. Removes dead tissues from the surface of the skin. Side effects of fibrinolysin ointment: redness, burning, and inflammation.

Main outcome variables

In this study, we will assess the effect of fibrinolysin on the size, depth, and type of open wound.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221112056478N1**

Registration date: **2022-11-20, 1401/08/29**

Registration timing: **prospective**

Last update: **2022-11-20, 1401/08/29**

Update count: **0**

Registration date

2022-11-20, 1401/08/29

Registrant information

Name

Syed Raees Abbas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 930 601 6389

Email address

raeesnaqvi45@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-26, 1401/09/05

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of open wound management via vacuum dressing with and without fibrinolysin

Public title

Comparison of open wound management with dressing with and without ointment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

all patients with the same type of open wound will be managed via Vacuum Dressing in the imam Khomeini hospital, Tehran, Iran from 2022 - 2023. all patients with similar size of the open wound which will be managed via Vacuum Dressing admitted to the imam Khomeini hospital, Tehran, Iran from 2022 - 2023.

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a clinical trial study in which, with the help of random allocation of eligible patients, patients are placed in two groups an interventional group and a control group. The blocking method is used for randomization and the numbering and tagging of blocks will be four. Blinding will be performed on patients and they will not be aware that they are in the intervention or control group. In addition, the selection of patients in each group will be available by the method.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding will be performed on patients and they will not be aware that they are in the intervention or control group. In addition, the selection of patients in each group will be available by the method.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics Committee in Research of Imam Khomeini Hospital Complex - Tehran University of Medical Scienc

Street address

Tehran, Quds town (west), between South Flamek and Zarafshan, Simai Iran St., Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th floor.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-09-03, 1401/06/12

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.122

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

Open Wound

ICD-10 code

S01

ICD-10 code description**Primary outcomes****1****Description**

Wound Healing with fibrinolysin

Timepoint

24 hours

Method of measurement

Imito measure application

Secondary outcomes

empty

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

Intervention group: Fibrinolysin Group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex, Tehran University of Medical Sciences

Full name of responsible person

Doctor Narjes Muhammadzadeh

Street address

Imam Khomeini Hospital Complex, Tehran University of Medical Sciences Tehran, Quds town (west), between South Flamek and Zarafshan, Simai Iran St., Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th floor.

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surg-depart-research@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Doctor Narjes Muhammadzadeh

Street address

Surgery Ward 5 - Imam Khomeini Hospital Complex, Tehran University of Medical Sciences, Tehran

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

No

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Syed Raees Abbas

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

to keep patients information safe, codes will be assigned to patients data instead of using patient's names.

Individual patient data will not be shared without approval from patient

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