

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of effects of heparin gel versus placebo on stage 2 pressure ulcers: a randomized controlled trial study

Protocol summary

Study aim

evaluation effects of heparin gel versus placebo in pressure ulcer

Design

The study population consisted of all patients with pressure ulcer hospitalized in the Clinical Research Development Unit of Imam Reza Hospital in Kermanshah. Fifty-eight patients will be included in the study by available method and will be randomly assigned to one of the study groups.

Settings and conduct

Imam Reza hospital, heparin and placebo pills will be prepared by a pharmacist who is unaware of patients allocation.

Participants/Inclusion and exclusion criteria

all patients with stage 2 pressure ulcer who sign the inform consent

Intervention groups

Identical carboxy-methyl cellulose base heparin or placebo gel will be prepared in pharmaceuticals lab. Heparin gel (200 Unite/g) applied daily for 30 days. All patients will received standard wound care and intervention (or placebo) will be added to standar therapy

Main outcome variables

In both groups, the wound will be examined during the days 1,3,7,14,21,30 by a trained and skilled wound dresser and its features (depth, size, wound discharge) will be carefully documented.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043993N1**

Registration date: **2019-12-25, 1398/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-25, 1398/10/04**

Update count: **0**

Registration date

2019-12-25, 1398/10/04

Registrant information

Name

foroud shahbazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3426 6780

Email address

foroud08@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-21, 1398/04/30

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects of heparin gel versus placebo on stage 2 pressure ulcers: a randomized controlled trial study

Public title

effects of heparin gel on pressure sore treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

all patients with pressure sore stage II

Exclusion criteria:

not sign informed consent active bleeding low platelet count

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomized double- blind (Patients and assessor)

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Blvd,

City

Kermanshah

Province

Kermanshah

Postal code

1673-67145

Approval date

2019-11-26, 1398/09/05

Ethics committee reference number

IR.KUMS.REC.1398.826

Health conditions studied

1

Description of health condition studied

Grade 2 Pressure Ulcer

ICD-10 code

L89

ICD-10 code description

Pressure ulcer

Primary outcomes

1

Description

Effects of heparin gel compared with placebo on pressure ulcer status (depth, size, and secretion)

Timepoint

1,3,7,14,21,30

Method of measurement

Depth, diameter, and wound secretion of both group will be evaluated until day-30 of treatment

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive heparin gel daily for one month

Category

Treatment - Drugs

2

Description

The control group will receive placebo gel daily for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Foroud Shahbazi

Street address

Parastar Blv

City

kermanshah

Province

Kermanshah

Postal code

1673-67145

Phone

+98 83 3427 6493

Email

foroud08@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

083-34276493

Phone

+98 83 3427 6489

Email

Foroud08@gmail.com

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

Yes

Title of funding source

Kermanshah 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**

Kerman University of Medical Sciences

Full name of responsible person

Foroud Shahbazi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Parastar Blve

City

kermanshah

Province

Kermanshah

Postal code

083-34276493

Phone

+98 83 3426 6780

Email

foroud08@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Foroud Shahbazi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Parastar blve

City

Kermanshah

Province

Kermanshah

Postal code

083-34276489

Phone

+98 83 3426 6780

Email

Foroud08@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Foroud Shahbazi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Parastar Blve

City

Kermanshah

Province

Kermanshah

Postal code

083-34276493

Phone

+98 83 3427 6489

Email

foroud08@gmail.com

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
No - There is not 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
Evaluation of effects of heparin gel versus placebo on

stage 2 pressure ulcers: a randomized controlled trial
study
When the data will become available and for how long
patients data without name
To whom data/document is available
All investigators
Under which criteria data/document could be used
according to our institution roles
From where data/document is obtainable
Principle Investigators
What processes are involved for a request to access data/document
contact with investigators
Comments