

# 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

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kermanshah

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## 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

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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

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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**  
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**