Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effect of hydrogel containing gentamicin on pressure ulcers

Protocol summary

Study aim
The aim of the study is to determine the effect of hydrogel containing gentamicin on pressure ulcer
Design
This study is a randomized controlled clinical trial with parallel groups and no blinding.
Settings and conduct
The research sample size consists of 105patients with grade 2 pressure ulcer(intervention group 90, control group 30) in Imam Reza hospital in Kermanshah city in 2020-2021
Participants/Inclusion and exclusion criteria
Physician and patient satisfaction, hydrogel and hydrogel containing gentamicin susceptibility,no wound infection,no skin disease,diabetes and kidney failure,age over 18,no drug use,earn points more than 18 from Braden scale،administration of nitroglycerin and immunosuppressive drugs، occurrence of pressure ulcer in order to National Pressure Ulcer Advisory Panel (NPUAP) scale،need for any surgery،need for debridement،bleeding
Intervention groups
The intervention in this study is using Hydrogel and Hydrogel containing gentamicin. In the control group, the intervention is the use of Comfeel dressing. The wound will be checked by push-scale on days 1,3,7,14,21,30
Main outcome variables
Healing of pressure ulcer

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181105041563N6**
Registration date: **2020-12-06, 1399/09/16**
Registration timing: **registered_while_recruiting**
Last update: **2020-12-06, 1399/09/16**
Update count: **0**
Registration date
2020-12-06, 1399/09/16

Registrant information
Name
Somayeh Mahdavikian
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-21, 1399/09/01
Expected recruitment end date
2021-03-21, 1400/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of hydrogel containing gentamicin on pressure ulcers

Public title
Evaluation the effect of hydrogel on pressure ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Consent of the physician and the patient to participate in

the study No addiction to drugs and alcohol, Insensitivity to hydrogels and gentamicin Absence of any signs of wound infection and skin disease Having aged over 18 years No diabetes, and kidney failure Stage 2 of The National Pressure Ulcer Advisory Panel (NPUAP) scale Lack of bleeding Earn points equal to 14-6 from Braden scale

Exclusion criteria:

Earn points more than 18 from Braden scale Administration of nitroglycerin and immunosuppressive drugs Occurrence of pressure ulcer in order to (The National Pressure Ulcer Advisory Panel (NPUAP) scale Need for any surgery Need for debridement Bleeding

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Qualified samples were entered into the study by convenience method and randomly divided into intervention groups (Hydrogel and Hydrogel containing gentamicin) and control. Blocks were done as follows: Hydrogel and Hydrogel containing gentamicin was assigned A and B codes respectively, and the control group received C code. The study blocks were ABC, ACB, BAC, BCA, CAB, CBA, BCC, CAB, CAB, and the ABC block was selected as the first block. Patients were assigned to Hydrogel and Hydrogel containing gentamicin, and control groups, respectively, and this method continued until the samples were completed.

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Kermanshah University of Medical Sciences, Shahid Beheshty Blv, Kermanshah University of Medical Sciences, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6715986479

Approval date

2019-09-04, 1398/06/13

Ethics committee reference number

IR.KUMS.REC.1398.655

Health conditions studied

1

Description of health condition studied

Pressure ulcer

ICD-10 code

L89

ICD-10 code description

Stage II decubitus ulcer

Primary outcomes

1

Description

Healing of pressure ulcer

Timepoint

Day one, three, seven, fourteen, twenty one and thirty of the study

Method of measurement

Push scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: in group 1, the wound will be dressed daily at 8:00 AM with hydrogel made by pharmacist researchers of Kermanshah University of Medical Sciences for 30 days, So that the hydrogel covers 2 mm from the wound surface and will be checked on the days of 1,3,7,14,21,30 by Push scale.

Category

Other

2

Description

Second intervention group: in group 2, the wound will be dressed daily at 8:00 AM with hydrogel containing gentamicin made by pharmacist researchers of Kermanshah University of Medical Sciences for 30 days,So that the hydrogel containing gentamicin covers 2 mm from the wound surface and will be checked on the

days of 1,3,7,14,21,30 by Push scale.

Category

Other

3

Description

Control group: in group 3 the wound will be dressed every two days at 8:00 AM with 1/2 of the hydrocolloid sheet dressing made by Coloplast Denmark for 30 days, and will be checked on the days of 1,3,7,14,21,30 by Push scale.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Somayeh Mahdavikian

Street address

Imam Reza hospital, Baghe Abrisham

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Somayeh.Mahdavikian@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshty Blv., Kermanshah, Iran

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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

Kermanshah University of Medical Sciences

Full name of responsible person

Somayeh Mahdavikian

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blv., Kermanshah, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable