Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of sucralfate 15% gel in decreasing of bedsore degree I & II , in bedridden patients of Sari Imam Khomeini hospital.

Protocol summary

Summary

Objectives: Evaluation the effect of Sucralfate 15% gel on degree I & II bedsore, in Sari Imam Khomeini hospital's patients Design: Parallel, double blind, placebo control, clinical trial Setting and conduction: In this study 30 cases and 30 controls of bedridden patients with bedsore will enroll accidentally to the study. Participants: Inclusion criteria: All of patients that have bedsore I &II degree; base on American Society of Anesthesiology protocols Exclusion criteria: Adverse reaction to the product; Or the bedsore degree increase to III and IV Intervention: During 7 days, all of the patients, will receive normal treatment including: frequent change position, daily washing and dressing, also case group will receive Sucralfate 15% gel and control group will receive placebo. Main outcomes: Each day ulcer will observe for discharge, color and size (Based on PUSH tool) .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107053014N5**
Registration date: **2012-05-02, 1391/02/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-05-02, 1391/02/13

Registrant information

Name

Shahram Ala

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of sucralfate 15% gel in decreasing of bedsore degree I & II , in bedridden patients of Sari Imam Khomeini hospital.

Public title

Investigating the effect of sucralfate 15% gel in decreasing of bedsore degree I & II

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All of patients that have bedsore I &II degree; base on American Society of Anesthesiology protocols Exclusion criteria: Adverse reaction to the product; Or the bedsore degree increase to III and IV

Age

No age limit

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics department of Mazandaran University of Medical Sciences
Street address
Ethics department of Mazandaran University of Medical Sciences, Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, sari, Mazandaran, Iran
City
Sari
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
203

Health conditions studied

1

Description of health condition studied
Bedsore
ICD-10 code
L89
ICD-10 code description
Decubitus ulcer and pressure area

Primary outcomes

1

Description
Discharge
Timepoint
7 days
Method of measurement
drainage

2

Description
Ulcer size
Timepoint
7 days
Method of measurement
ruler

3

Description
Ulcer color
Timepoint
7 days
Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
There are 30 case with bedsore rank 1 or 2 in this study that will receive Sucralfate 15% gel during 7 days. Then the ulcer will observe for size, color and discharge.
Category
Treatment - Drugs

2

Description
There are 30 control with bedsore rank 1 or 2 in this study that will receive placebo gel during 7 days. Then the ulcer will observe for size, color and discharge.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Sari
Full name of responsible person
Dr Shahram Ala
Street address
Imam Khomeini Hospital, Amir-Mazandarani street, Sari, Mazandaran, Iran
City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences, Vice chancellor for research

Full name of responsible person
Dr Ahmadali Enayati

Street address
Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, Sari, Mazandaran, Iran

City
Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mazandaran University of Medical Sciences, Vice chancellor for research

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Sari Faculty of Pharmacy

Full name of responsible person
Motahare Ahmadi

Position
Pharmacy student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Associated professor of clinical pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty