

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Studying the clinical effects of semisolid dosage form using *Falcaria vulgaris* on bed sore patients

Protocol summary

Study aim

The aim of this study is to evaluate the effects of semisolid dosage form prepared from *Falcaria vulgaris* on bed sore patients

Design

All patients who admitted in Emam khomeini hospital at Kermanshah University of Medical Sciences which suffering from bed sore or any other that admitted with any sing of bed sore will selected and guide the accompanying patients about the herbal medicine. They informed that the drug will be added to previous treating.

Settings and conduct

All patients who admitted in Emam khomeini hospital at Kermanshah University of Medical Sciences which suffering from bed sore or any other that admitted with any sing of bed sore will selected and guide the accompanying patients about the herbal medicine. They informed that the drug will be added to previous treating.

Participants/Inclusion and exclusion criteria

All admitted patients in Emam Khomeini hospital Kermanshah University of Medical Sciences suffering from bed sore

Intervention groups

Selected patients and their companions will take information about the investigational drug, then the drug administered on bedsores and injuries

Main outcome variables

During treatment, wounds will be scanned and evaluated according to the size and deep. the wound samples will be prepared and study the pathological specifications by a pathology specialist. according to braden criteria different parameters like sensory perception, skin humidity, physical activity, mobility, nutrition condition, friction and skin tensile will be studied. pass medical history and habit history (alcoholic and opium addiction) will be interested in selected patients. the pain score of patients will be studied if it is possible

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130722014106N6**

Registration date: **2018-12-31, 1397/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

Registration date

2018-12-31, 1397/10/10

Registrant information

Name

Reza Tahvilian

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6482

Email address

rtahvilian@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the clinical effects of semisolid dosage form using *Falcaria vulgaris* on bed sore patients

Public title

Studying the clinical effects of semisolid dosage form using *Falcaria vulgaris* on bed sore patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with bed sore in Emam Khomeini hospital Kermanshah University of medical sciences

Exclusion criteria:

patient under anti neoplastic drug therapy patients receiving immunosuppressive drugs patients with cancer at end stage

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Other

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

No. 5116, Emam Khomeini hospital Naglieh Avenu

City

kermanshah

Province

Kermanshah

Postal code

6718743161

Approval date

2018-10-10, 1397/07/18

Ethics committee reference number

IR.kums.rec. 1397.589

Health conditions studied

1

Description of health condition studied

bed sore

ICD-10 code

S01.00XD

ICD-10 code description

Unspecified open wound of scalp, subsequent encounter

Primary outcomes

1

Description

length and wide of wound, exodus and type of tissue

Timepoint

first day, first to sixth week

Method of measurement

taking pic. and measuring the size of wound dimensions, type of tissue by clinical evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: bed sore patients

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini hospital

Full name of responsible person

Dr. Hossein Amiri

Street address

No. 5116, Emam Khomeini hospital Naglieh Avenu

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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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
Dr. Neda Shahbazi
Position
Quality improvement office
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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

no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available