

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Clinical evaluation of an herbal semisolid dosage form of Scrophularia for scar treatment

#### Protocol summary

##### Summary

This study will be done with aim to investigate the effectiveness of a species of Scrophularia affecting wound repair. This is non-blinded clinical trial. The study population will be included all patients who due to injury from an accident, bed sores and diabetic ulcers will refer to the dermatologist in Kermanshah city. A total of 30 eligible patients that more than 3 days has not passed from wounding and the size of the wound has not caught more than 10% of body surface, will be selected in available method and will be assigned to tow experimental and control groups. Patients with secondary infection; Pregnant or lactating women; Patients treated with immunosuppressant drugs and patients with infected wounds that require treatment with antibiotics; Patients who take drugs with wound healing properties such as corticosteroid will excluded from the study. In this study, formulation of 10% of this herb will be used as a vanishing cream in experimental group. No intervention will be done in control group and usual cream will be used. Then its effect on the wound healing as a reduction of wound area (in percent) during the 7, 14 and 28 days will investigated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092014333N57**  
Registration date: **2016-10-26, 1395/08/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-10-26, 1395/08/05

##### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2016-10-16, 1395/07/25

##### Expected recruitment end date

2017-07-16, 1396/04/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical evaluation of an herbal semisolid dosage form of Scrophularia for scar treatment

##### Public title

The effect of a species of Scrophularia on wound repair

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: More than 3 days has not passed from wounding; The size of the wound has not caught more than 10% of body surface. Exclusion criteria: Patients with secondary infection; Pregnant or lactating women; Patients treated with immunosuppressant drugs and

patients with infected wounds that require treatment with antibiotics; Patients who take drugs with wound healing properties such as corticosteroid.

#### **Age**

From **3 years** old to **60 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **30**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not 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**

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

##### **City**

Kermanshah

##### **Postal code**

#### **Approval date**

2016-05-11, 1395/02/22

#### **Ethics committee reference number**

kums.rec.1395.81

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Bedsore

#### **ICD-10 code**

L89.2

#### **ICD-10 code description**

Stage III decubitus ulcer

## **Primary outcomes**

### **1**

#### **Description**

Wound area

#### **Timepoint**

Baseline, days of 7, 14 and 28

#### **Method of measurement**

Visit by dermatologist

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Formulation of 10% of this herb will be used as a vanishing cream in experimental group for a month.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

No intervention will be done in control group and usual cream will be used

#### **Category**

Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

DDoctor Ebrahimi Clinic

##### **Full name of responsible person**

Maryam Ghaderi

##### **Street address**

Hajidaee Clinic, Golestan Square

##### **City**

Kermanshah

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

##### **Full name of responsible person**

Koroush Hamzehee

##### **Street address**

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

##### **City**

Kermanshah

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Kermanshah University of Medical Sciences

**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**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Reza Tahvilian

**Position**

Pharmaceutics

**Other areas of specialty/work**

**Street address**

School of Pharmacy, University of Medical Sciences, ParastarBoulevard

**City**

Kermanshah

**Postal code**

**Phone**

+98 83 3427 6482

**Fax**

**Email**

rtahvilian@kums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Maryam Ghaderi

**Position**

Student of Pharmacy

**Other areas of specialty/work**

**Street address**

School of Pharmacy, University of Medical Sciences, ParastarBoulevard

**City**

Kermanshah

**Postal code**

**Phone**

+98 83 3427 6482

**Fax**

**Email**

m\_ghadery91@yahoo.com

**Web page address**

**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*