# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 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)

**Phone**

+98 15 1354 3083

**Email address**

sala@mazums.ac.ir

**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**
**Street address**
Payambar azam complex-Farahabad BLVD
**City**
Sari
**Postal code**
**Phone**
+98 212346378
**Fax**
**Email**
sasanpoorneda@gmail.com; m7_ahmadi@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Faculty of pharmacy-Mazandaran University of Medical Sciences
**Full name of responsible person**
Dr shahram Ala
**Position**
Associated professor of clinical pharmacy
**Other areas of specialty/work**
**Street address**
Faculty of Pharmacy,Payambar Azam Complex-Farahabad BLVD
**City**
Sari
**Postal code**
**Phone**
+98 15 1354 3083
**Fax**
**Email**
sala@mazums.ac.irsh204ala@yahoo.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
faculty of pharmacy, Mazandaran University of Medical Sciences
**Full name of responsible person**
Dr shahram Ala
**Position**
Assosiated Professor of clinical pharmacy
**Other areas of specialty/work**
**Street address**
Faculty of pharmacy,Payambar azam complex-Farahabah BLVD
**City**
Sari
**Postal code**
**Phone**
+98 15 1354 3083
**Fax**
**Email**
sala@mazums.ac.ir, sh204ala@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*