# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Effect of chamomile versus placebo on first-degree pressure ulcer in patients hospitalized in ICU: a double-blind randomized clinical trial

## Protocol summary

**Study aim**
To assess the effect of chamomile versus placebo on first-degree pressure ulcer in patients hospitalized at ICU
**Design**
This a double-blind randomized clinical trial, phase II, in which 64 eligible patients will be randomly assigned to the intervention and control groups
**Settings and conduct**
The eligible patients with first-degree pressure ulcer who will hospitalized in ICU at Azahra, Amin or Imam Hossein Hospitals during the study period will be enrolled in the trial
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age of 18 to 70 years; Hospitalized in ICU; Having first-degree pressure ulcer; Exclusion criteria: A history of allergy or cutaneous hypersensitivity; Any hypersensitivity to chamomile
**Intervention groups**
Intervention group: Topical ointment including chamomile active ingredient daily for 7 days Control group: Topical ointment including placebo (Vaseline) daily for 7 days
**Main outcome variables**
Primary outcome: Improvement of ulcer on 4 and 7 days after intervention through physical examination

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20120215009014N205**
Registration date: **2018-02-03, 1396/11/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-03, 1396/11/14**
Update count: **0**
**Registration date**
2018-02-03, 1396/11/14

**Registrant information**
**Name**
Jalal Poorolajal
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2018-01-21, 1396/11/01
**Expected recruitment end date**
2018-04-21, 1397/02/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effect of chamomile versus placebo on first-degree pressure ulcer in patients hospitalized in ICU: a double-blind randomized clinical trial

**Public title**
Effect of chamomile versus placebo on first-degree pressure ulcer in patients hospitalized in ICU
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**

Age of 18 to 70 years Hospitalized in ICU Having first-degree pressure ulcer

**Exclusion criteria:**

A history of allergy or cutaneous hypersensitivity Any hypersensitivity to chamomile

**Age**

From **18 years** old to **70 months** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment of the patients to the intervention and control groups through drawing of lots

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology, Isfahan University of Medical Sciences, Hezar Jarib Ave

**City**

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**Province**

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**Postal code**

8174673461

**Approval date**

2017-12-11, 1396/09/20

**Ethics committee reference number**

IR.IUMS.REC.1396.699

## Health conditions studied

**1**

**Description of health condition studied**

Pressure ulcer

**ICD-10 code**

L89

**ICD-10 code description**

Pressure ulcer

## Primary outcomes

**1**

**Description**

Improvement of ulcer

**Timepoint**

On 4 and 7 days after intervention

**Method of measurement**

Through physical examination

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: Topical ointment including chamomile active ingredient daily for 7 days

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Topical ointment including placebo (Vaseline) daily for 7 days

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Azahra Hospital

**Full name of responsible person**

Maryam Hashemi

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School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar jarib Ave.

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## Sponsors / Funding sources

### 1

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Esfahan University of Medical Sciences
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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**
Esfahan 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**
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Esfahan University of Medical Sciences
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Maryam Hashemi
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available