

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

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

#### Protocol summary

2018-02-03, 1396/11/14

#### 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

#### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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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**

Isfahan

**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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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Ahmad Movahedian Attar  
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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

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Maryam Hashemi  
**Position**  
Nursing Student  
**Latest degree**  
Master  
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Nursery  
**Street address**

## Person responsible for scientific inquiries

#### Contact

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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