

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Clinical Trial of comparison effect of mint gel and placebo gel on incidence rate of pressure ulcer in hospitalized patients with head injury in neurosurgical ICU

Protocol summary

Summary

This study evaluates the effect of mint gel on prevention of pressure ulcer. The study is a randomized, Triple-blind (patients, researchers and analyst), placebo-controlled, two centered. Supervisor is only person that is aware from gel types. The study population include patients with head injury admitted to intensive care unit. Inclusion criteria: Hospitalization in intensive care due to head injury; transfer to the intensive care unit with endotracheal tube; absence of any underlying disease; No history of allergy to the mint; the lack of pressure ulcers on arrival; Glasgow Coma Scale (GCS) 8 or less. Exclusion criteria: Death or transfer of the patient to ward within 48 hours; patient's unwillingness to cooperate; Sensitivity to mint gel. Sample size includes 70 patients. After arrival to ICU in test group, three times a day (once per shift). we will use a layer of mint gel on skin of areas are at risk for pressure ulcers such as pelvic and bone prominences along routine nursing cares. This work will continue until patient staying in ICU (in 5, 10 and up to 14 days). Control group is similar to test group but for this group we will use of placebo gel. Incidence rate of pressure ulcer will be evaluated by using prepared checklists.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402098665N3**

Registration date: **2014-03-07, 1392/12/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-07, 1392/12/16

Registrant information

Name

Hassan Babamohamadi

Name of organization / entity

Semnan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2014-03-06, 1392/12/15

Expected recruitment end date

2014-12-06, 1393/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of comparison effect of mint gel and placebo gel on incidence rate of pressure ulcer in hospitalized patients with head injury in neurosurgical ICU

Public title

Effect of mint gel on prevention of pressure ulcer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Hospitalization in intensive care due to head injury; Patient's transfer to the intensive care unit

with endotracheal tube; absence of any underlying disease such as cardiovascular, lung, kidney, diabetes and other chronic disease; No history of allergy to plants in the mint family; The lack of pressure ulcers on arrival; Glasgow Coma Scale (GCS) 8 or less on arrival; Patients with multiple trauma if they do not have restrictions on postural changes are enrolled. Exclusion Criteria: Death or transfer of the patient within 48 hours; patient's unwillingness to cooperate a few days after admission; Sensitivity to mint gel; inflammation of mucous membrane (the site of gel application); refusing for continuing study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Vice
Chancellor of Research and Technology, Basidj Blv,
Semnan, Iran

City

Semnan

Postal code

3519899951

Approval date

2014-02-19, 1392/11/30

Ethics committee reference number

92/408037

Health conditions studied**1****Description of health condition studied**

Decubitus ulcer

ICD-10 code

L89

ICD-10 code description

Decubitus ulcer and pressure area

Primary outcomes**1****Description**

Pressure ulcer

Timepoint

Once a day

Method of measurement

Checklists prepared of Bruden tool, present clinical status and National Pressure Ulcer Advisor Panel guide

Secondary outcomes

empty

Intervention groups**1****Description**

After patient arrival to ICU in test group, 3 times a day (once per shift) used a layer of mint gel on skin of areas are at risk for pressure ulcers such as pelvic and bone prominences along routine nursing cares. This work will continue until patient staying in ICU (in 5, 10 and up to 14 days).

Category

Prevention

2**Description**

After patient arrival to ICU in control group, 3 times a day (once per shift) used a layer of placebo gel on skin of areas are at risk for pressure ulcers such as pelvic and bone prominences along routine nursing cares. This work will continue until patient staying in ICU (in 5, 10 and up to 14 days).

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz Namazi Hospital

Full name of responsible person**Street address****City**

Shiraz

2

Recruitment center

Name of recruitment center

Shaheed Rajaei Hospital

Full name of responsible person**Street address****City**

Shiraz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Dr Raheb Ghorbani

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Semnan University of Medical Sciences, Vice
Chancellor of Research and Technology, Basidj Blv,
Semnan, Iran

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Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Semnan 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**Name of organization / entity**

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Full name of responsible person

Hassan Babamohamadi

Position

Assistant Professor

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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