

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison the effect of the topical Plantago major hydro-alcoholic extract versus placebo on treatment of grade1 pressure ulcer in patients with paralysis secondary to brain stroke: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To compare the effect of the topical Plantago major hydro-alcoholic extract versus placebo on treatment of grade1 pressure ulcer in patients with paralysis secondary to acute stroke Design: a triple blind randomized clinical trial. Setting and conduct: The eligible patients with paralysis secondary to brain stroke who will refer to Farshchian Hospital during the study period will be enrolled into the trial. Inclusion criteria: Complete bedrest patients with paralysis secondary to brain stroke; grade1 pressure ulcer. Exclusion criteria: Grade 2 pressure ulcer; sensitivity to Plantago and its products; Intervention group: Using topical Phenytoin cream 1% on the grade 1 pressure ulcers once a day for 2 weeks plus Plantago major hydro-alcoholic extract once a day for 2 weeks. Control group: Using topical Phenytoin cream 1% on the grade 1 pressure ulcers once a day for 2 weeks plus placebo once a day for 2 weeks Primary outcome: Assessing the grade 2 pressure ulcer or higher grades 2 weeks after treatment through physical examination. Secondary outcome: Assessing local reactions such as rash, hives, or redness 2 weeks after treatment through physical examination. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609209014N117**

Registration date: **2016-09-22, 1395/07/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-09-22, 1395/07/01

Registrant information

Name

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2016-10-06, 1395/07/15

Expected recruitment end date

2016-10-08, 1395/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of the topical Plantago major hydro-alcoholic extract versus placebo on treatment of grade1 pressure ulcer in patients with paralysis secondary to brain stroke: a triple blind randomized clinical trial

Public title

Comparison the effect of the topical Plantago major hydro-alcoholic extract versus placebo on treatment of grade1 pressure ulcer in patients with paralysis secondary to brain stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Complete bedrest patients with paralysis secondary to brain stroke; grade1 pressure ulcer. Exclusion criteria: Grade 2 pressure ulcer; sensitivity to Plantago and its products;

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-09-17, 1395/06/27

Ethics committee reference number

IR.UMSHA.REC.1395.295

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Assessing the grade 2 pressure ulcer or higher grades

Timepoint

2 weeks after treatment

Method of measurement

through physical examination

Secondary outcomes

1

Description

Assessing local reactions such as rash, hives, or redness

Timepoint

2 weeks after treatment

Method of measurement

through physical examination

Intervention groups

1

Description

Using topical Phenytoin cream 1% on the grade 1 pressure ulcers once a day for 2 weeks plus Plantago major hydro-alcoholic extract once a day for 2 weeks

Category

Treatment - Drugs

2

Description

Using topical Phenytoin cream 1% on the grade 1 pressure ulcers once a day for 2 weeks plus placebo once a day for 2 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Zahra Niroomandi

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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Hamadan

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 the Technology, Hamadan
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

Farshchian Hospital

Full name of responsible person

Zahra Niroomandi

Position

Student of Pharmacology

Other areas of specialty/work

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Web page address

Person responsible for updating data

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Name of organization / entity

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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