

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of therapeutic effect of Quercus infectoria gall on pressure ulcer in patients with cerebral palsy due stroke

Protocol summary

Summary

Objectives: determination of therapeutic effects of Q. infectoria gall extract on pressure ulcer in patients with stroke in Farshchian Hospital of Hamadan in the years 96-97. Design: a double blind randomized clinical trial with control and placebo. Setting and conduct: the eligible hospitalized patients in department of neurology and ICU of Farshchian Hospital with cerebral palsy due stroke will be enrolled into the trial. Inclusion criteria: patients with 2/5 or more of paralysis due one-way stroke and with pressure ulcer; patients who score 16 or less in Norton scale. Exclusion criteria: patient death or transfer to another health center; patient with necrotic wound due pressure ulcer at the beginning of the study; positive response to allergy test of Q. infectoria gall extract; progression of pressure ulcer to higher stages during the study. Intervention group: topical application of Phenytoin once daily and topical application of Q. infectoria gall 12 hours later. Control group: topical application of Phenytoin once daily and topical application of placebo 12 hours later. Primary outcome: progression of pressure ulcer to higher grades than initiation of treatment. Secondary outcome: assessing local reactions such as rash, hives, or redness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080435420N2**

Registration date: **2017-08-17, 1396/05/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-17, 1396/05/26

Registrant information

Name

Dara Dastan

Name of organization / entity

School of Pharmacy, Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Thchnology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of Quercus infectoria gall on pressure ulcer in patients with cerebral palsy due stroke

Public title

Evaluation of therapeutic effect of Quercus infectoria gall on pressure ulcer in patients with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with 2/5 or more of paralysis

due one-way stroke and with pressure ulcer; patients who score 16 or less in Norton scale. Exclusion criteria: patient death or transfer to another health center; patient with necrotic wound due pressure ulcer at the beginning of the study; positive response to allergy test of Q. infectoria gall extract; progression of pressure ulcer to higher grades during the study.

Age

From **37 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **94**

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 committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2017-07-10, 1396/04/19

Ethics committee reference number

IR.UMSHA.REC.1396.307

Health conditions studied

1

Description of health condition studied

Pressure ulcer

ICD-10 code

L89.9

ICD-10 code description

Decubitus ulcer and pressure area, unspecified

Primary outcomes

1

Description

Grade of pressure ulcer

Timepoint

At baseline and then daily for two weeks

Method of measurement

Through physical examination

Secondary outcomes

1

Description

Assessing local reactions such as rash, hives, or redness

Timepoint

24 hours later

Method of measurement

Through physical examination

Intervention groups

1

Description

Intervention: local application of Phenytoin cream 1% once daily in areas susceptible to ulcer (sacrum; iliac; spinal cord; elbow; waist; shoulder; auricle; buttock; heel and ankle) to the extent that cover the wound area and local application of Q. infectoria gall extract in the cream tube that is similar to placebo at 12 hours later for two weeks.

Category

Treatment - Drugs

2

Description

Control: local application of Phenytoin cream 1% once daily in areas susceptible to ulcer (sacrum; iliac; spinal cord; elbow; waist; shoulder; auricle; buttock; heel and ankle) to the extent that cover the wound area and local application of placebo in the cream tube that is similar to drug at 12 hours later for two weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Masoud Ghiasian

Street address

Farshchian Hospital, Mirzadeh Eshgi Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Science, Shaheed
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 and 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

School of Pharmacy

Full name of responsible person

Dara Dastan

Position

Ph.D of Phytochemistry, Assistant Professor

Other areas of specialty/work

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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