

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of topical ointment of *Centella asiatica* on partial thickness burning (A randomized clinical trial)

Protocol summary

Summary

Several dermatological effects of *Centella asiatica* including surgical and burning wound healing, increase of collagen and Fibronectin, blood flow in connective tissue and antimicrobial, anti-inflammatory and antioxidant properties, makes possible topical using it for treatment of burning and wound. This study is aimed to evaluate the effect of solution derived from *Centella asiatica* on partial thickness burning in patients referred to Velayat burning events center, Rasht. This is a double blind randomized clinical trial in which both physicians and patients are not aware of content of administrative drug in groups. Of patients with partial thickness burning and lower than 10% burning in the limbs, between 14-65 years old, with stable general condition, without history of concomitant major disease and history of drug consumption, 60 patients will be entered in the study. After confirming inclusion criteria and rule out of exclusion criteria, they were divided randomly into two remedial intervention and control groups. Control group will give routine treatment (Silver Sulfadiazine 1%) and intervention group will give solution derived from *Centella asiatica*. Patients will be evaluated as severity of pain and surface of burning in entering time, 2, 7 and 14 days after giving treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100614915N1**

Registration date: **2014-10-11, 1393/07/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-11, 1393/07/19

Registrant information

Name

Amin Saeidinia

Name of organization / entity

Medicinal plants research center of student Basij,
Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1669 0099

Email address

a.saeidynia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of topical ointment of *Centella asiatica* on partial thickness burning (A randomized clinical trial)

Public title

Effect of *Centella asiatica* on burning treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: every partial thickness burning with less than 10% involved body and being in limbs; time of burning less than 48 hours; No other injury except of burning lesion and have general health body; age

between 14 to 60 years Exclusion criteria: Existence of every cerebro-vascular diseases; cardiovascular diseases; endocrine diseases; liver diseases; renal diseases; history of abuse in alcohol or drugs; using antibiotic (oral or parenteral) at the same time; steroid or other immunosuppressive drug; burning due to lightning arresting; electrical instruments ; local burning of hand

Age

From **14 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research assistance of Guilan University of Medical Sciences- Ethics Comitee

Street address

Research assistance of Guilan University of Medical Sciences, top of Iran radiator building, end of flying bridge, Imam Khomeini boulevard, Rasht, Iran

City

Rasht

Postal code

Approval date

2013-12-07, 1392/09/16

Ethics committee reference number

1920341317

Health conditions studied

1

Description of health condition studied

Partial thickness burning

ICD-10 code

T20-T25

ICD-10 code description

Burn of first degree of shoulder and upper limb, except wrist and hand

Primary outcomes

1

Description

Subjective symptoms

Timepoint

Day 2,7 and 14 after initiating treatment

Method of measurement

It will be scored by below symptoms: dryness: 1=yes, 0=no; itching: 1=yes, 0=no; irritation: 1=yes, 0=no

2

Description

Objective symptoms

Timepoint

Day 2,7 and 14 after initiating treatment

Method of measurement

It will be scored by below symptoms: Flexibility: 0=no, soft=1, yielding=2, stiff=3, sticky=4; Height: normal=0, 1-2mm=1, 3-4mm= 2, 5-6mm=3, >6mm=4; Vasculature: normal=0, pinky=1, red= 2, amethystine=3; Pigmentation: normal=0, mild=1, moderate=2, severe=3/ 0-4= lack of objective symptoms, 4-8= mild, 8-12= moderate, 12-14= severe

3

Description

Surface of burning

Timepoint

Day 2,7 and 14 after initiating treatment

Method of measurement

By evaluation of morphometric features with image analyzer software

4

Description

Severity of pain

Timepoint

Day 2,7 and 14 after initiating treatment

Method of measurement

By using Visual Analogue Score (VAS)

5

Description

Added at 2015-10-02: re-epithelialization

Timepoint

Added at 2015-10-02: from day 0 to complete of re-epithelialization

Method of measurement

Added at 2015-10-02: examination and observation with surgeon and sub-specialist of burning

6

Description

Added at 2015-10-02: Complete Healing

Timepoint

Added at 2015-10-02: from day 0 to complete of complete healing of scar

Method of measurement

Added at 2015-10-02: examination and observation with surgeon and sub-specialist of burning

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: using topical solution derived from Centella asiatica

Category

Treatment - Drugs

2

Description

Control group: treatment with Silver Sulfadiazine 1%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat burning events center, Rasht

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr. Javad Golchai

Street address

Dermatology Department, Razi hospital, Sardare Jangal Street, Rasht, Guilan, Iran

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Amin Saeidinia

Position

Medical Student

Other areas of specialty/work

Street address

Medical faculty, Guilan University, 10th kilometer Tehran road, Rasht, Guilan, Iran

City

Rasht

Postal code

Phone

+98 13 1669 0099

Fax

Email

a.saeidynia@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr. Javad Golchai; Dr. Ardalan Pasdaran

Position

Professor; Assistant Professor

Other areas of specialty/work

Street address

Razi hospital, Sardare Jangal Street, Rasht, Guilan, Iran/ Pharmacy faculty, Guilan University of Medical Sciences complex, Saravan-Fouman street, end of Lakan road, Rasht, Guilan, Iran

City

Rasht

Postal code

Phone

+98 13 1555 0028

Fax

Email

amin.saeidynia@gmail.com;

ardalan.pasdar@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Faeze Keihanian

Position

Medical Student

Other areas of specialty/work

Street address

Medical faculty, Guilan University, 10th kilometer
Tehran road, Rasht, Guilan, Iran

City

Postal code

Phone

+1 316690099

Fax

Email

faezekeihanian@yahoo.com

Web page address

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