

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of Centella asiatica ointment on third degree burns in patients to the burn center of burns in the province of Rasht in 2018

Protocol summary

Study aim

The effect of centella asiatica ointment on third degree burning wound

Design

Two parallel group double blind randomized controlled trial

Settings and conduct

This study will be performed due to importance of burning and will be held in Velayat hospital and double blind clinical trial in which physician and patient will be blind to type of drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: age more than 18 years, Third degree burning wounds, involvement of lesser than 25% of total body surface area, surface of lesser than 1 cm² in burning wound area, burning in limbs and trunk, time from burning lesser than 48 hours, lack of any other lesion except burning, general and mental health
Exclusion criteria are: no consent to participate, lack of ability to do follow up, existence of any cerebrovascular, cardiovascular, endocrine, liver and kidney disorders, history of abuse of alcohol or substances, concurrent use of antibiotic (topical and oral), steroid or immunosuppressive drugs, pregnancy

Intervention groups

group receiving centella asiatica ointment and group receiving silver sulfadiazine

Main outcome variables

time to re-epithelialization and time to complete healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131006014915N2**

Registration date: **2018-09-13, 1397/06/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-13, 1397/06/22**

Update count: **0**

Registration date

2018-09-13, 1397/06/22

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

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Centella asiatica ointment on third degree burns in patients to the burn center of burns in the province of Rasht in 2018

Public title

The effect of herbal ointment containing centella asiatica on third degree burning wound

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Third degree burning wounds involvement of lesser than 25% of total body surface area surface of lesser than 1 cm² in burning wound area burning in limbs and trunk time from burning lesser than 48 hours lack of any other lesion except burning general and mental health more than 18 years old

Exclusion criteria:

no consent to participate lack of ability to do follow up existence of any cerebrovascular, cardiovascular, endocrine, liver and kidney disorders history of abuse of alcohol or substances concurrent use of antibiotic (topical and oral) steroid or immuno-suppressive drugs pregnancy

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

burning wound in every limb and in trunk or against limb

Randomization (investigator's opinion)

Randomized

Randomization description

four blocked, block randomization by using a, b, c, d block in randomization, in a way that groups will be allocated in considered intervention group by determined respect and equally.

Blinding (investigator's opinion)

Double blinded

Blinding description

blinding will be done by pocket and physician and patient will be blinded to type of drugs

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

First floor, Research and Technology assistant, Shahid Siadati street, Namjoo Street

City

Rasht

Province

Guilan

Postal code

4188794755

Approval date

2018-09-04, 1397/06/13

Ethics committee reference number

IR.GUMS.REC.1397.201

Health conditions studied

1

Description of health condition studied

Third degree burn

ICD-10 code

T21.3

ICD-10 code description

Burn of third degree of trunk

2

Description of health condition studied

Third degree burn

ICD-10 code

T22.3

ICD-10 code description

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

Primary outcomes

1

Description

Re-epithelialization

Timepoint

0, 3 and 14 days and then the day epithelialization completed

Method of measurement

examination

2

Description

complete healing of derm

Timepoint

0, 3 and 14 days and then the day epithelialization completed

Method of measurement

examination

Secondary outcomes

1

Description

visual analogue scale

Timepoint

0, 3 and 14 days after burn

Method of measurement

pain ruler

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

Intervention group: using centella asiatica ointment

Category

Treatment - Drugs

2**Description**

Control group: using silver sulfadiazine

Category

Treatment - Drugs

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

Velayat burning center

Full name of responsible person

Mohammad Reza Mobayen

Street address

Velayat Hospital, Namjoo Street

City

Rasht

Province

Guilan

Postal code

4193713191

Phone

+98 13 3336 8714

Email

vellayat.info@gmail.com

Web page address

<http://www.gums.ac.ir/velayat>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

Street address

First floor, Research and Technology assistant, Shahid Siadati street, Namjoo Street

City

Rasht

Province

Guilan

Postal code

4188794755

Phone

+98 13 3333 5821

Email

research@gums.ac.ir

Web page address

<http://www.gums.ac.ir/research/>

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

Yes

Title of funding source

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Amin Saeidinia

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

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

City

Rasht

Province

Guilan

Postal code

3363

Phone

+98 13 1669 0099

Fax**Email**

a.saeidynia@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Mobayen

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Velayat Hospital, Namjoo street

City

Rasht

Province

Guilan

Postal code

4193713191

Phone

+98 13 3336 8714

Email

maziar.mobayen@gmail.com

4193713191

Phone

+98 13 3336 8714

Email

mahditaleghan@chmail.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data can be shared after non-labeled of name of participants

When the data will become available and for how long

after publishing the article till unlimited time

To whom data/document is available

scientific and academic institutes

Under which criteria data/document could be used

after sending request and after evaluation it will be available

From where data/document is obtainable

with corresponding scientific author

What processes are involved for a request to access data/document

sending email of request to corresponding author, evaluation and after confirmation of it, sending necessary data

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mahdi Nabaei

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Velayat Hospital, Namjoo Street

City

Rasht

Province

Guilan

Postal code