

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Safety and Efficacy of Carbon Selenium Complex in Second Degree Burns: A Randomized Clinical Trial

Protocol summary

Summary

In this study, the safety and the efficacy of Carbon Selenium Complex (CSeC) ointment in second degree burn ulcers is compared with the standard treatment, Silver Sulfadiazine (SSD). This study will be conducted at the departments of Burn and Plastic Surgery at Ghotbeddin University Hospital of Shiraz University of Medical Sciences, Shiraz and at Sina University Hospital of Tabriz University of Medical Sciences, Tabriz. In each center, 100 out-patient males and females with superficial thermal burns involving less than 20 percent of the body surface treated within 24 hours of the burn in a hospital burn unit will be selected for the study. Then, the patients will be allocated randomly to intervention and control groups. In intervention group, study medication, Carbon Selenium Complex 1.5%, will be applied as a thin smear of approximately 2 mm in quantities depending on the size of the burn to the surface of the greatest wounds in size after the burn is washed with normal saline. In the control group, the wounds will be covered with silver sulfadiazine 1% impregnated gauze pieces after washing them with normal saline and will be re-applied daily. In both groups, dressing of the wounds will be done every day. Study wounds (the greatest wounds according to their surface area) will be evaluated, beginning at first day of treatment and at least every other day thereafter. During each visit, epithelialization of the study wounds will be assessed by the same investigator. Photos will be taken prior to the first dressing, and every second day after that. The clinical assessment of study wounds will be performed every other day and includes inflammation and healing tendency. Each study wound will be evaluated until re-epithelialized or autografted. The investigator's global assessment of anti-infective efficacy, quality of wound healing, handling of the preparation, and patients assessed wound pain, itching, and sensation during change of dressing, the number of days taken for complete re-epithelialization to occur will

be recorded. Overall responses to therapy will be rated in terms of wound bacterial count and time for epithelialization of partial thickness burns.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808062587N2**

Registration date: **2010-01-27, 1388/11/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-01-27, 1388/11/07

Registrant information

Name

Parviz Hosseini

Name of organization / entity

Parsroos Company

Country

Iran (Islamic Republic of)

Phone

+98 21 8837 0763

Email address

dr.p.hosseini@gmail.com

Recruitment status

Recruitment complete

Funding source

Parsroos Biotechnology Company

Expected recruitment start date

2009-12-05, 1388/09/14

Expected recruitment end date

2010-05-05, 1389/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and Efficacy of Carbon Selenium Complex in Second Degree Burns: A Randomized Clinical Trial

Public title

Assessing Carbon Selenium Complex healing effect on partial thickness burns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Each involved patient should be stable in condition and not need resuscitation; Thermal flame or scald injury; Admitted within 24 hours after the injury; Clean noninfected wound as diagnosed by the attending physician; The wounds with comparable size and treatment prior to the screening visit; The size of the burn wounds to be assessed is required to be at least 15 cm² but no more than 300 cm²; In case of more than one burned wound in the same individual as described above, the wound with the greatest surface area will be selected for study; The burn area less than 20% and more than 1% total body surface area (TBSA); Age from 18 to 65 years; Weight up to 100 kg; Patients will be eligible for the study if written informed consent is obtained from each participant. Exclusion Criteria: Burn injury occurrence >24 h prior to commencement of treatment; Full-thickness burns; Wounds noted to be contaminated or infected; Burns in special areas such as the face, fingers, axillary, perineal or inguinal region, deep body folds, or a distinctive adipose tissue region and finally, massive burns in joints; Drug allergy histories or known hypersensitivity to silver sulfadiazine or any other ingredient of the study medications; Contraindications for the use of topical preparations containing silver sulfadiazine; Pregnancy; Alcohol or drug abuse; Significant organ dysfunctions such as renal failure, CHF, and liver dysfunction; Cancer; Vascular diseases; Immunosuppressive disorders; Inhalation injury; Simultaneous burn and trauma; Abnormal liver enzymes and total bilirubin > 1.5 times of normal upper limit

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **200****Randomization (investigator's opinion)**

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Avicenna Research Institute Ethics Committee

Street address

Avicenna Research Institute, Shahid Beheshti University, Evin, Tehran, Iran

City

Tehran

Postal code**Approval date**

2009-10-27, 1388/08/05

Ethics committee reference number

88/6285

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

Second Degree Burn

ICD-10 code

T31.1

ICD-10 code description

Burns involving 10-19% of body surface

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

The number of days until wound closure ($\geq 90\%$ re-epithelialization).

Timepoint

Study wounds will be evaluated, beginning at day 2 after treatment and at least every other day thereafter.

Method of measurement

By wound re-epithelialization assessments, the percentage of wounds closure will be assessed by the same investigator through visual estimation, to the nearest 5%, up to 90% and by single percentage points above 90%. The appearance of new tissue at the wound edge can be measured in centimeters or by the percentage of wound coverage. Then, the number of days taken for complete re-epithelialization to occur will be recorded.

Secondary outcomes

1

Description

The analgesic effect

Timepoint

Every other day from first day of treatment

Method of measurement

By visual analogous scale (VAS), itching (5-point scale), and sensation during change of dressing (4-point scale)

2

Description

The quality of wound healing

Timepoint

Every other days from third day of treatment

Method of measurement

According to elasticity, smoothness, and appearance of the wound

3

Description

Adverse effects

Timepoint

During treatment period

Method of measurement

According to any toxicity evidence or dermal abnormal sign indicating rashes, post positive swelling or inflammation, redness, irritation, pain, itching, necrosis, scar formation, and systemic adverse events

4

Description

The number of partial thickness healed wounds in the 21st day of intervention.

Timepoint

The healing rate will be assessed every other day.

Method of measurement

It will be determined by a surgeon.

5

Description

Wounds surface areas.

Timepoint

Every other day

Method of measurement

It will be defined by wounds planimetry which will be performed by a surgeon.

6

Description

The number of dressing changes.

Timepoint

Every day.

Method of measurement

By counting the number of dressing changes.

7

Description

Wounds Infection.

Timepoint

1st, 2nd, 3rd, 10th, and 17th days.

Method of measurement

According to positive or negative bacterial cultures.

8

Description

The burn complications (infection, scar formation, hypopigmentation)

Timepoint

Every other day from third day of treatment

Method of measurement

According to bacteriological assessments and appearance of the wounds

9

Description

The cosmetic results

Timepoint

Every other day from third day of treatment

Method of measurement

According to scar formation, hypopigmentation and the investigator idea

10

Description

Number of days until the first appearance of granulation tissue

Timepoint

Every other day from third day of treatment

Method of measurement

It will be determined during each visit by a surgeon

11

Description

The failure to heal

Timepoint

Every other day from third day of treatment

Method of measurement

According to very slow healing rate (5-6 weeks) or the number of study wounds that require autografting

Intervention groups

1

Description

Carbon Selenium Complex 1.5%, once daily, will be applied as a thin smear of approximately 2 mm in quantities depending on the size of the burn to the surface of the greatest wounds in size after the burn is washed with normal saline

Category

Treatment - Drugs

2

Description

Silver Sulfadiazine 1% impregnated gauze pieces after washing them with normal saline and will be re-applied daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Burn Research Center

Full name of responsible person

Dr. Aliakbar Mohammadi

Street address

Shiraz Burn Research Center, Ghotbeddin University Burn Hospital, Shiraz University of Medical Sciences, Shiraz, Iran

City

Shiraz

2

Recruitment center

Name of recruitment center

Department of Burn and Surgery, Sina University Hospital

Full name of responsible person

Dr. Hemmat Maghsoudi

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Department of Burn and Surgery, Sina University Hospital, Tabriz University of Medical Sciences, Tabriz, Iran

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Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Parsroos Biotechnology Company

Full name of responsible person

Dr. Kamran Motamedi

Street address

No 568, 13th Alley, Hormozan St., Shahrak-e-Gharb, Tehran, Iran.

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Parsroos Biotechnology Company

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

Dr. Parviz Hosseini

Position

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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