Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Iran (Islamic Republic of)
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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 (≥ 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Parsroos Biotechnology Company
Full name of responsible person
Dr. Kamran Motamedi
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No 568, 13th Alley, Hormozan St., Shahrak-e-Gharb, Tehran, Iran.
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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

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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