# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Identification of Maximum Tolerated Dose for topical form of Carbon Selenium Complex in healthy volunteers

## Protocol summary

**Summary**

Carbon Selenium Complex (CSeC), as a topical drug, has been investigated as an innovation in prevention and treatment of complications of burn. In this study, we will test different doses CSeC to find appropriate dosage of the drug for phase II, III and IV clinical trial on the treatment of heat burn injuries. This study is designed as a phase I clinical trial, without control group and as an open label study in two steps from 21st of April till 21st of June. 15 healthy volunteers will contribute in 5 equivalent groups after signing informed consent. Physical examination and laboratory tests will be performed for all participants to rule out underlying diseases or any other serious cutaneous diseases. All participants receive equal dose of CSeC and the dosage of the drug will increase from group 1 to 5. In the first step, group 1, 2, and 3 will begin the study and group 4 and 5 will remain for the next step. Hydration, PH, pigmentation, sebum, trans-epidermal water loss, erythema, and side effects will be measured as main outcomes.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138811253267N1**
Registration date: **2010-06-12, 1389/03/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2010-06-12, 1389/03/22

**Registrant information**

**Name**

Sedigheh Madani

**Name of organization / entity**

Parsroos

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8837 0763

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s.madani@parsroos.com

**Recruitment status**

**Recruitment complete**

**Funding source**

parsroos company

**Expected recruitment start date**

2010-04-21, 1389/02/01

**Expected recruitment end date**

2010-07-21, 1389/04/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Identification of Maximum Tolerated Dose for topical form of Carbon Selenium Complex in healthy volunteers

**Public title**

phase I clinical trial of topical Carbon Selenium Complex

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: signing informed consent, no extremities edema or other abnormal signs, normal lab test including: Liver function tests ( AST, ALT, Alkaline Phosphatase, and Bilirubin); serum creatinine; Random blood sugar level

**Age**

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

**Gender**

Both

**Phase**
1
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **15**
**Randomization (investigator's opinion)**
N/A
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Single
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Pharmaceutical Sciences Research Center, Tehran University of Medical Sciences
**Street address**
Pharmaceutical Sciences Research Center,Tehran University of Medical Sciences,Enghelab Square, Tehran
**City**
Tehran
**Postal code**
1417614411
**Approval date**
2009-11-04, 1388/08/13
**Ethics committee reference number**
88/425/190/ص

## Health conditions studied

### 1

**Description of health condition studied**
heat burn injury
**ICD-10 code**
T20, T21,
**ICD-10 code description**
Burns and corrosions of external body surface, specified by site

## Primary outcomes

### 1

**Description**
Sebum measurment
**Timepoint**
at first session (before and 30 min after application), at last session
**Method of measurement**
by using C.K tool(courage-khazaka)

### 2

**Description**
hydration
**Timepoint**
at first session (before and 30 min after application), at last session
**Method of measurement**
by using C.K tool(courage-khazaka)

### 3

**Description**
PH
**Timepoint**
at first session (before and 30 min after application), at last session
**Method of measurement**
by using C.K tool(courage-khazaka)

### 4

**Description**
pigmentation
**Timepoint**
at first session (before and 30 min after application), at last session
**Method of measurement**
by using C.K tool(courage-khazaka)

### 5

**Description**
erythema
**Timepoint**
at first session (before and 30 min after application), at last session
**Method of measurement**
by using C.K tool(courage-khazaka)

### 6

**Description**
trans epidermal water loss (TEWL)
**Timepoint**
at first session (before and 30 min after application), at last session
**Method of measurement**
by using C.K tool(courage-khazaka)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Carbn Selenium Complex oinment will be applied on anterion of forearm in a 5*5 cm surface daily for 14 days. No derressing will be needed and no washing for 6 hours will be required.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Razi hospital
**Full name of responsible person**
Dr. Alireza Firooz
**Street address**
Center for Research and Training in Skin Disease and Leprosy, Tehran University of Medical Sciences. 79 Taleghani Ave ,Tehran , 14166, Iran
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Parsroos Company
**Full name of responsible person**
Dr Kamran Motadedi
**Street address**
No 568,13th Alley, Hormozan St., Shhrsk-e-gharb, Tehran, Iran
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Parsroos 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**
Center for Research and Training in Skin Diseases and Leprosy
**Full name of responsible person**
Alireza Firooz
**Position**
Dermatologist, Associate Professor
**Other areas of specialty/work**
**Street address**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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Medical doctor
**Other areas of specialty/work**
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**Email**
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**Web page address**
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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*