

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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

##### Email address

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 measurement

#### 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 anterior 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

79 Taleghani Avenue, Tehran university of medical science, Center for Research and Training in Skin Diseases and Leprosy, Tehran, 14166, Iran

#### City

Tehran

#### Postal code

14155-6383

#### Phone

+98 21 8897 8190

#### Fax

+98 21 8896 3804

#### Email

alifiruz@yahoo.com; firozali@sina.tums.ac.ir

#### Web page address

<http://crtsdl.tums.ac.ir>

## Person responsible for scientific 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

79 Taleghani Avenue, Tehran university of medical science, Center for Research and Training in Skin Diseases and Leprosy, Tehran, 14166, Iran

#### City

Tehran

#### Postal code

14155-6383

#### Phone

+98 21 8897 8190

#### Fax

+98 21 8896 3804

#### Email

alifiruz@yahoo.com; firozali@sina.tums.ac.ir

#### Web page address

<http://crtsdl.tums.ac.ir>

## Person responsible for updating data

### Contact

#### Name of organization / entity

ParsRoos company

**Full name of responsible person**

Seyedeh Sedigheh Madani

**Position**

Medical doctor

**Other areas of specialty/work****Street address**

No.538, 13th alley, hormozan street, shahrak-e-gharb,  
Tehran, Iran

**City**

Tehran

**Postal code**

1466793143

**Phone**

+98 21 8837 0763

**Fax**

+98 21 8837 0763

**Email**

sedigheh\_madani@yahoo.com

**Web page address**

www.parsroos.com

**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*