

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Study the effect of Granulocyte colony stimulating factor (G-CSF) influence on neurological and cardiac toxicity caused by carbon monoxide in patients with carbon monoxide poisoning in two groups drug and placebo

Protocol summary

Summary

In this double blind clinical trial, 40 patients poisoned with carbon monoxide eligible to enter the study after informed consent were randomly divided into two groups drug and placebo. After diagnosis of carbon monoxide poisoning during the 12 hours of the onset, colony stimulating factor granulocyte (G-CSF) or placebo at a dose of 180 µg / Kg was given as a continuous infusion over 72 hours. In the times before and after 0.5, 1, 2, 5, 8, 12, 24, 48 hours after administration of G-CSF, blood samples from patients were taken and G-CSF concentration using ELISA was evaluated. For patients Holter monitoring ECG closed and within 24 hours of poisoning all arrhythmia's, especially ventricular arrhythmia's were recorded. Changes in T and ST segment related to ischemia were recorded. patient's vital signs every 4 hours during the first 24 hours, every 6 hours during the second and third days were recorded. Score (NIHSS) in Day 1 (pre-intervention), 3 and 30 after intervention and Modified Rankin and Barthel score at day 30 were measured and recorded. Index STR percentage, serum (TPI) in 3, 12, 24, 48 and 72 hours after intervention were recorded. The concentration of serum GFAP, Myeloperoxidase, S100β, IL6, MBp using ELISA , serum carboxyhemoglobin with GC-mas and (Brain MRI) before the intervention and at 1, 3 and 30 after intervention were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607232083N7**
Registration date: **2017-04-28, 1396/02/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-28, 1396/02/08

Registrant information

Name

Seyed Reza Mousavi

Name of organization / entity

Imam Reza Hospital, Mashhad University of Medical science

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 8973

Email address

mousavir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences grants

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of Granulocyte colony stimulating factor (G-CSF) influence on neurological and cardiac toxicity caused by carbon monoxide in patients with carbon monoxide poisoning in two groups drug and placebo

Public title

Study the effect of Granulocyte colony stimulating factor (G-CSF) influence on neurological and cardiac toxicity caused by carbon monoxide in patients with carbon monoxide poisoning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of carbon monoxide poisoning based on clinical and laboratory findings; poisoning severity of moderate to severe based on the concentration of carboxyhemoglobin and clinical symptoms (NIHSS); poisoned patients must be enrolled within 24 hours of incidence of toxicity; Age between 18 and 70 years Exclusion criteria: Pregnancy; Other Simultaneous poisoning; Burn; the history of neurosurgical and head trauma During the past 4 weeks; multiple trauma 6 - ischemic stroke or hemorrhagic during the last 4 weeks; Malignancies; chronic inflammatory diseases; hematologic malignancies; allergies and or elevated titers of antibodies against erythropoietin and high blood pressure 180/110; cardiovascular disease; any previous cerebrovascular lesions

Age

From **14 years** old to **70 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Azadi Square, Ferdowsi University campus

City

Mashhad

Postal code**Approval date**

2016-11-13, 1395/08/23

Ethics committee reference number

IR.MUMS.SP.1395.73 950789

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

Carbon monoxide poisoning

ICD-10 code

T58

ICD-10 code description

Toxic effect of carbon monoxide

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

S100B serum concentration

Timepoint

Day 1 pre-intervention, 3 and 30 after intervention

Method of measurement

Elysa kit

2**Description**

NIHSS

Timepoint

Day 1 pre-intervention, 3 and 30 after intervention

Method of measurement

NIHSS scor chart

3**Description**

Barthel Index

Timepoint

Day 30 after intervention

Method of measurement

Barthel Index chart

4**Description**

TI serum concentration

Timepoint

In 3,12, 24, 48 and 72 h after intervention

Method of measurement

Elysa kit

5**Description**

Cardiac arrhythmias

Timepoint

During 24 h after intervention

Method of measurement

ECG holter monitor

Secondary outcomes

1

Description

G-CSF serum concentration

Timepoint

in times 0.5, 1, 2, 5, 8, 12, 24, 48 h after intervention

Method of measurement

elysa kit

2

Description

vital signs: BP, HR, T and RR

Timepoint

Every 4 hours during the first 24 hours, every 6 hours during the second and third days

Method of measurement

By nurse

3

Description

Modified Rankin score

Timepoint

In day 30 after intervention

Method of measurement

Modified Rankin score chart

4

Description

Carboxyhemoglobin serum concentration

Timepoint

In Day1 (pre-intervention), 3 and 30 after intervention

Method of measurement

GC-mas-mas Headspace

5

Description

Glial Fibrillary Acidic protein(GFAP) serum concentration

Timepoint

Day1 (pre-intervention), 3 and 30 after intervention

Method of measurement

Elysa kit

6

Description

Myeloperoxidase serum concentration

Timepoint

Day1 (pre-intervention), 3 and 30 after intervention

Method of measurement

Elysa kit

7

Description

Myelin basic protein

Timepoint

Day1 (pre-intervention), 3 and 30 after intervention

Method of measurement

Elysa kit

8

Description

Cerebral ischemia

Timepoint

Day1 (pre-intervention), 3 and 30 after intervention

Method of measurement

Brain MRI

9

Description

Headache, asthenia, memory impairment, sleep disorders, trouble concentrating, visual disturbances and behavioral disorders

Timepoint

Day1 (pre-intervention), 3 and 30 after intervention

Method of measurement

By specialist

Intervention groups

1

Description

Granulocyte colony-stimulating factor (G-CSF) at dose 180 µg / Kg, one-third of the total dose as a loading dose within 20 minutes and the remaining two-thirds dose for continuous infusion at a constant rate during the 72 hours prescribed to patients

Category

Treatment - Drugs

2

Description

100 ml of sodium chloride isotonic injection of a third of the total dose as the dose loading within 20 minutes, and two-thirds of the remaining dose for continuous infusion at a constant rate over 72 hours administrated in carbon monoxide poisoned patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency and the part poisoning of Imam Reza hospital

Full name of responsible person

DR.seyed reza mousavi

Street address

St. Ibn Sina - Imam Reza square

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Management and technology assistance of Mashhad university of medical sciences, school of pharmac

Full name of responsible person

Dr. Amir houshang mohammadpour

Street address

Azadi Square campus of Ferdowsi University, School of Pharmacy

City

mashhad

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

Yes

Title of funding source

Management and technology assistance of Mashhad university of medical sciences, school of pharmac

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Seyed Reza Mousavi

Position

Associate professor forensics

Other areas of specialty/work
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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