Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 pressure180/110; 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 houers 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 Fibrilary 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 poisining of Imam Reza hospital
Full name of responsible person
DR.seyed reza mousavi
Street address
St. Ibn Sina - Imam Reza square
City

Mashhad

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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Person responsible for scientific inquiries

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Full name of responsible person

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Professor of Clinical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Atena Pourtaji

Position

Toxicology PhD student

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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