

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of administering high doses of intravenous vitamin C in severe traumatic brain injuries

Protocol summary

Study aim

Determining the effect of administering a high dose of intravenous vitamin C on the outcome of severe traumatic brain injuries

Design

The clinical trial has a control group, with parallel groups, randomized, phase 3, the number of samples in each group is estimated to be 59, which, by including 15% drop during the study, the number of samples for each group is 69. Allocation of samples to intervention groups with using method Random blocks of 4 are done

Settings and conduct

This study is conducted on patients with severe brain damage and low level of consciousness who need to be hospitalized in ICU according to the order of a specialist doctor. Samples are collected from patients referred to the Trauma Referral Center of Shahid Rajaei Hospital in Qazvin Province Group A: Standard treatment along with daily 100 (mg/kg/day) vitamin C in 500 cc of normal saline divided into 3 doses for 3 days as intravenous injection and after 3 days, 3 grams of vitamin C daily in 500 cc of normal saline divided into 3 doses for one week is given to the patient. Group B: standard treatment

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient age between 27 and 12 years, patients with brain damage severe ($GCS \leq 8$), patients who have not undergone surgery, informed consent of the first degree relatives of the patients Exclusion criteria: end stage renal diseases, hemochromatosis patients, chronic liver diseases, chronic kidney diseases, history of kidney stones, Allergy to vitamin C, pregnancy and breastfeeding.

Intervention groups

Group A: standard treatment plus vitamin C Group B: standard treatment Standard treatment includes head positioning, narcotic pain treatment, magnesium hydroxide for gastrointestinal function, heparin therapy, ulcer prophylaxis, and normal saline

Main outcome variables

Changes in the patient's clinical status and consciousness based on the GCS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230530058344N1**

Registration date: **2023-06-08, 1402/03/18**

Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**

Update count: **0**

Registration date

2023-06-08, 1402/03/18

Registrant information

Name

Mehdi Valipuor Jamnani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

mdrc46@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of administering high doses of intravenous vitamin C in severe traumatic brain injuries

Public title

The effect of administering high doses of intravenous vitamin C in severe traumatic brain injuries

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient age 18 to 60 years Patients with severe brain damage ($GCS \leq 8$) Patients who have not undergone surgery Informed consent of the first degree relatives of the patients and completion of the consent form

Exclusion criteria:

Chronic Kidney Disease End-Stage Renal Disease (ESRD) Pregnancy and breastfeeding Hemochromatosis patients Reluctance to cooperate In the study Chronic liver diseases (cirrhosis, hepatitis, etc.) History of kidney stones Vitamin C allergy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients diagnosed with brain damage need to be hospitalized in ICU are the statistical population of this study. Patients were randomly assigned to one of the two treatment groups A (standard treatment plus vitamin C) or group B (standard treatment) are assigned. Sampling is done using the available method. Allocating the samples to the intervention groups using the method of 4 random blocks with the Block Balanced Randomization method in the form of AABB, ABBA, ABAB, BBAA, BAAB, BABA blocks will be placed together based on the table of random numbers.

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**

Ethics committee of qazvin University of Medical Sciences

Street address

Research and Technology deputy ,Mavaddat Alley,Shahid Beheshti Blvd,Qazvin

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Postal code

3413996134

Approval date

2023-05-24, 1402/03/03

Ethics committee reference number

IR.QUMS.REC.1402.037

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

severe traumatic brain injuries

ICD-10 code

S09.7

ICD-10 code description

Multiple injuries of head

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

Changes in the patient's clinical status and consciousness based on the GCS scale

Timepoint

At the time of entering the ICU, the second day, the fourth day and during transfer to the ward

Method of measurement

Glasgow Coma Scale

Secondary outcomes**1****Description**

The duration of the patient's stay in the ICU and the hospital

Timepoint

When discharged from the hospital

Method of measurement

Counting days of hospitalization

2**Description**

8 and 28 day mortality rate
Timepoint
8 and 28 days after ICU admission
Method of measurement
Counting days of hospitalization

Intervention groups

1

Description

Intervention group: Patients with standard treatment (head positioning, narcotic pain treatment, MOM for digestive function, heparin therapy, ulcer prophylaxis and normal saline serum 500 cc) daily 100 mg/kg/day vitamin C in 500 cc of normal saline divided into three doses They are given intravenously for three days, and after three days, the amount of vitamin C received is 3 grams per day in 500 cc of normal saline divided into three doses for one week.

Category

Treatment - Drugs

2

Description

Control group: standard treatment (head positioning, narcotic pain treatment, MOM for digestive function, heparin therapy, ulcer prophylaxis and normal saline serum 500 cc)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Trauma Referral Center of Shahid Rajaei Hospital

Full name of responsible person

Mehdi Valipour Jamnani

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Safdari Ave., Padegan Blvd

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Sponsors / Funding sources

1

Sponsor

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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

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mehdi Valipour Jamnani

Position

Resident

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available