Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 ≤ 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 ≤ 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 cooperateIn 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

City
Qazvin

Province
Qazvin

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

Street address

Safdari Ave., Padegan Blvd

City

Qazvin

Province

Qazvin

Postal code

3413996134

Phone

+98 28 3333 5800

Email

hosrajaee@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Mirhashemi

Street address

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

City

Qazvin

Province

Qazvin

Postal code

3413996134

Phone

+98 28 3333 7006

Email

researchdpt@qums.ac.ir

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

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Bahonar street

City

Qazvin

Province

Qazvin

Postal code

34197-58911

Phone

+98 28 3333 6001

Email

mdrc46@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Mehdi Valipour Jamnani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
University campus building, Bahonar Blvd

City
Qazvin

Province
Qazvin

Postal code
34197-58911

Phone
+98 28 3333 6001

Email
mdrc46@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Mehdi Valipour Jamnani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
University campus building, Bahonar Blvd

City
Qazvin

Province
Qazvin

Postal code
34197-58911

Phone
+98 28 3333 6001

Email
mdrc46@yahoo.com

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