

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of high dose of vitamin C on brain acute phase biomarker in patients with diffuse axonal brain injury .

Protocol summary

Study aim

The effect of high dose of vitamin C on acute phase biomarker of cerebral S100B protein in patients with diffuse axonal brain injury

Design

Clinical trial with control group ,with parallel groups , double-blind ,randomised ,phase 3 on 90 patients.Patients are randomly divided into two groups based on RANDOM software.

Settings and conduct

Information of T.B.I patients referred to Poursina Medical Center in 1401 is registered.Drug and Placebo group receive Vitamin C and Normal Saline respectively by continuous infusion from C.V.C .

Participants/Inclusion and exclusion criteria

Adult patients aged 16 years and <60 years and moderate and severe head injury on the Glasgow Coma score of 4 to 12 (23) and acceptance with diagnosis of diffuse brain injury and S06.2 in the ICD-10 classification within the first 24 hours of injury and radiological diagnosis of diffuse axonal injury.

Intervention groups

Drug group will receive vitamin C in a dose of 10 g / 100 ml daily as a continuous infusion (4.166 ml per hour) for 7 days intravenously.Control group will receive normal saline in a dose of (100 ml daily with the same color and shape as the drug) as a continuous infusion (4.166 ml per hour) for 7 days intravenously by central venous catheter.

Main outcome variables

To evaluate the main consequence, The S100B protein level of blood samples was taken on the first, third and eighth day of hospitalization and after separating the serum in a freezer at -80 ° C and will be stored by the commercial kit until the S100B protein is measured. Treatment outcomes and complications including acute oxalate nephropathy (death, plant life, severe lower disability, upper severe disability, lower moderate disability, upper moderate disability, inferior good

recovery, good upper functional recovery) were also present in the study groups at zero ,one and three months intervals and will be registered based on GOS score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210123050123N1**

Registration date: **2022-03-30, 1401/01/10**

Registration timing: **prospective**

Last update: **2022-03-30, 1401/01/10**

Update count: **0**

Registration date

2022-03-30, 1401/01/10

Registrant information

Name

Mehdi Dehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-09-11, 1401/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of high dose of vitamin C on brain acute phase biomarker in patients with diffuse axonal brain injury .

Public title

Effect of vitamin C on head trauma ;

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult patients aged 16 years or older and <60 years
Moderate to severe diffuse axonal injury with a Glasgow coma score of 4 to 12 Admission with diagnosis of diffuse brain injury as defined by ICD-10 S06.2 within the first 24 hours of injury Radiological diagnosis of diffuse axonal brain injury

Exclusion criteria:

Patients with a specific pathology on a CT scan of the brain that is inconsistent with the diagnosis of DAI
Patients with acute and chronic liver injuries Patients with acute and chronic renal insufficiency and those at high risk for urinary stones. people with underlying conditions such as uncontrolled diabetes, high blood pressure , chronic obstructive pulmonary disease , blood diseases , Malnutrition or unusual diets. Previous central nervous system injury , concomitant spinal cord injury, space-occupying lesions requiring emergency evacuation
Patients whose guardians do not consent to participate in the study patients with a previous diagnosis of severe psychiatric illness or substance abuse patients with shock or hypoxia or Cardiopulmonary arrest following trauma.

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Identified patients are randomly divided into two groups of drugs and placebo based on a random block, and the method of selecting patients is that each patient is randomly assigned to the hospital by an emergency physician who is familiar with the type of study but not familiar with assignment of patients . They are divided into two groups, A and B, based on RANDOM software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The attending physician will inject the type of drug or placebo based on the choice of A and B at the time of the study and the drug will be written as codes A and B. The injector, patient and donor have no information about its type. Patients' legal guardians will also be given the necessary explanations regarding the objectives of the study and the method of conducting the study, and they will be informed that they may receive one of the types of drugs A or B and will obtain their informed consent.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Gilan Ethics Committee for biosafety& laboratory Standards

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Guilan University of Medical Sciences , Namjo ave, Rasht Town, Gilan, IRI

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Province

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Postal code

419371311

Approval date

2022-03-09, 1400/12/18

Ethics committee reference number

IR.GUMS.REC.1400.629

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

Description of patients with diffuse brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

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

Acute Brain Biomarker S100B Protein

Timepoint

First ,Third and Eighth Day

Method of measurement

ELISA kit S100B

Secondary outcomes

1

Description

Glasgo Coma Score

Timepoint

The begining of the intervention,Third and Eighth Day

Method of measurement

Glasgo Coma Score Table

2

Description

Acute Oxalate Nephropathy

Timepoint

The beginning of Study,Third and Eighth day

Method of measurement

Measurement of urinary output,oxalate amount and specific gravity of urine,urea ,uric acid and creatinin of plasma

3

Description

Glasgow Outcome Score

Timepoint

The beginning of study,first and Third month

Method of measurement

Glasgow Outcome Score Scale

Intervention groups

1

Description

Intervention group: Intervention group: Receiving vitamin C in a dose of 10 g / 100 ml daily as a continuous infusion (4.166 ml / h) for 7 days

Category

Treatment - Other

2

Description

Control group: ormal saline (100 ml with the same color and shape as the drug) as a continuous infusion (4.166 ml / h) daily for 7 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Therapeutic Training Center

Full name of responsible person

Anoush Dehnadi Moghadam

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Poursina Hospital,Namjo ave,Rasht Town,Gilan,IRI

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

dr,Nemat-o-lah Ahangar

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Anoush Dehnadi Moghadam

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Published in prestigious journals

When the data will become available and for how long

2 years

To whom data/document is available

Professors and students

Under which criteria data/document could be used

Publication of a scientific article

From where data/document is obtainable

The person in charge of the project

What processes are involved for a request to access data/document

Processing and receiving

Comments