

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of treatment with (Hydrocortisone+ Ascorbic acid+ Neurobion) on the prognosis of multiple trauma patients in comparison with control group

Protocol summary

Study aim

Determining the effect of drug combination (hydrocortisone + ascorbic acid + neurobion) on the prognosis of multiple trauma patients.

Design

In this triple blind randomized controlled clinical trial phase 3, 70 multiple trauma patients were distributed in two groups of 35 intervention and control using random allocation software. In the intervention group, the drug combination of vitamin C + hydrocortisone + neurobion is prescribed and the control group receives a placebo.

Settings and conduct

This triple blind clinical trial study is performed in 1400 in Ayatollah Kashani Hospital in Isfahan. In this study, patients, researchers and evaluators of the outcome of treatment are unaware about the type of drug received by patients,

Participants/Inclusion and exclusion criteria

In this study, multiple trauma patients over the age of 18 with an injury severity greater than 15 are included in the study. Pregnant patients, history of adrenal insufficiency, history of weakened immune system, corticosteroid therapy within the last 6 months, G6PD patients, history of oxalate nephropathy, oliguria or anuria, and patients with a history of allergy or anaphylaxis to any of the drugs hydrocortisone or ascorbic acid or ascorbic acid Are not studied.

Intervention groups

Intervention group: In this group, 1.5 grams of vitamin C is injected every 6 hours for 4 days and 50 mg of hydrocortisone every 6 hours for 6 days and one neurobion ampoule is injected every 4 hours for 4 days. Control group: In the group, normal saline is injected as a placebo.

Main outcome variables

Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201116049410N1**

Registration date: **2021-07-14, 1400/04/23**

Registration timing: **prospective**

Last update: **2021-07-14, 1400/04/23**

Update count: **0**

Registration date

2021-07-14, 1400/04/23

Registrant information

Name

SeyedTaghi Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3233 0066

Email address

st_hashemi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2022-03-18, 1400/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of treatment with (Hydrocortisone+ Ascorbic acid+ Neurobion) on the prognosis of multiple trauma patients in comparison with control group

Public title

Effect of treatment with (Hydrocortisone+ Ascorbic acid+ Neurobion) on multiple trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patient (age ≥ 18 years) Multiple trauma patients Injury Severity Score greater than 15

Exclusion criteria:

Pregnancy History of adrenal insufficiency Patients with history of Immunosuppression Corticosteroid therapy within the last six months G6PD patients Hhistory of oxalate nephropathy Oliguria or anuria Known allergy to vitamin C, hydrocortisone, neurobion

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by simple randomization method. To do this, 70 prepared cards are written on 35 letters of letter A and on 35 other Tides of letter B and the cards are thrown into the box and shuffled well. When each patient enters the intensive care unit, one of the nurses who is not awar about the study, is asked to bring out a card. According to what is written on the card, patients are placed in the intervention or control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is a three-blind study and patients, researchers and outcome evaluators are unaware of the type of combination received. The drug combination of the two groups in similar packages is prepared by one of the personnel of the intensive care unit who is not under study and is provided to the executor of the project for use.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Ayatollah Kashani street

City

Isfahan

Province

Isfahan

Postal code

8434193474

Approval date

2020-10-14, 1399/07/23

Ethics committee reference number

IR.MUI.MEd.REC.1399.518

Health conditions studied

1

Description of health condition studied

multiple trauma

ICD-10 code

T07

ICD-10 code description

Unspecified multiple injuries

Primary outcomes

1

Description

General condition of the patient

Timepoint

Every day

Method of measurement

SOFA score

2

Description

Duration of hospitalization in the intensive care unit

Timepoint

At the time of leaving the Border Special Cases section

Method of measurement

The time interval between entering and leaving the intensive care unit

3

Description

Ventilation time

Timepoint

One time, at the extubation time
Method of measurement
Calculate the number of days connected to the ventilator

4

Description
Prognosis of the disease
Timepoint
Time to leave the intensive care unit
Method of measurement
Determining the patient's recovery status or death

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group receive 1.5 g of vitamin C every 6 hours for 4 days, hydrocortisone 50 mg every 6 hours for 7 days, neurobion two ampoules every 12 hours for 4 days.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group receive a placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Arash Masoudpour
Street address
Sofeh street, Alzahra hospital
City
Isfahan
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Postal code
8434193474
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arash1360@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Research faculty, Hezar Jerib street
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Isfahan
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Isfahan
Postal code
8434193474
Phone
+98 31 3791 3070
Email
Sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Arash Masoudpour
Position
resident
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Department of Anesthesiology, Alzahra hospital, Soffeh street
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Isfahan
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Isfahan
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Phone
36692174
Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Seyed Taghi Hashemi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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st_hashemi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ali Mehrabi

Position

Statistical Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Research faculty, school of medicine, Hezar Jerib
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The plan belongs to a government agency and cannot be
shared.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available