

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of injectable vitamins E and C on serum cortisol levels, Interleukin-6 and duration of hospitalization in patients with severe traumatic lung contusion: Randomized Controlled Clinical Trial

Protocol summary

Study aim

Evaluation of the effect of injectable vitamin E and Con serum cortisol interleukin-6, ABG, CRP and duration of hospitalization in patients with severe pulmonary contusion, and patients with at least 2 rib fractures

Design

Clinical trial with control group with 4 parallel groups of double-blind randomized phase 3 on 200 patients. Excel software was used for refinement

Settings and conduct

At Baqitullah Hospital in Tehran and Shariati Hospital in Kashan, 200 patients with chest trauma are randomly divided into 4 groups of 50 people. And vitamin E 100 for 3 days - and the fourth group take distilled water (patients are unaware of the type of drug) Then the inflammatory factors of interleukin 6 and arterial gases and inflammatory protein C and the length of hospitalization of patients between these 4 groups are examined.

Participants/Inclusion and exclusion criteria

Admission: Traumatized individuals over 12 years of age with a fracture of at least 2 ribs or lung contusion proven by CT scan images Exclusion: Patients that dont want to participate .

Intervention groups

The first group receives 100 units of vitamin E for 3 consecutive days The second group receives 500 grams of vitamin C for 3 consecutive days The third group receives 100 units of vitamin E and 500 grams of vitamin C for 3 consecutive days The fourth group receives 1distilled water for 3 consecutive days

Main outcome variables

متغیرها شامل پروتیین التهابی سی ; گاز شریانی خونی ; اینترلوکین ۶ وکورتیزول سرم و مدت بستری بیماران در بیمارستان

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200731048260N2**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Benyamin Seyfari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2259 6152

Email address

seyfari@ptsoc.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-17, 1400/07/25

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of injectable vitamins E and C on serum cortisol levels, Interleukin-6 and duration of hospitalization in patients with severe traumatic lung contusion: Randomized Controlled Clinical Trial

Public title

The effect of injectable vitamins E and C on serum cortisol levels, Interleukin-6 and duration of hospitalization in patients with severe traumatic lung contusion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

trauma patients with at least 2 broken ribs trauma patients with lung contusions based on ct scan pictures

Exclusion criteria:

patients under 12 patients that dont want to participate

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **192**

Randomization (investigator's opinion)

Randomized

Randomization description

We divide 1 to 200 into 4 groups randomly with the help of Excel (randomize between) and based on that, we divide the patients admitted to the study into these 4 groups. In a way, people themselves are not aware of the mentioned wedge

Blinding (investigator's opinion)

Double blinded

Blinding description

Trauma patients admitted to the study will not have any information about the type of substance received and will be explained that the drug used is harmless . The person who first tests the laboratory results also does not know the type of drug or placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of baqiyatallah hospital

Street address

NO28 . JAHANTAB AVE .TEHRAN.

City

tehran

Province

Tehran

Postal code

1939883614

Approval date

2021-03-02, 1399/12/12

Ethics committee reference number

IR.BMSU.BAQ.REC.1399.065

Health conditions studied

1

Description of health condition studied

Trauma patients with rib fracture and lung contusions

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Interlukin 6

Timepoint

first ,second and third day of addmition

Method of measurement

Labrotory

2

Description

c reactive protein (crp)

Timepoint

first ,second and third day of addmition

Method of measurement

Labrotory

3

Description

Serum cortisol

Timepoint

first ,second and third day of addmition

Method of measurement

Labrotory

4

Description

Atrial BI00d Gasses (ABG)

Timepoint

first ,second and third day of addmition

Method of measurement

Lab test

5

Description

Duration of hospitalization

Timepoint

Upon clearance

Method of measurement

Based on the number of days of hospitalization

Secondary outcomes

1

Description

Duration of hospitalization in the intensive care unit

Timepoint

When leaving the intensive care unit

Method of measurement

Based on the number of hospitalization days

Intervention groups

1

Description

Intervention group1: 50 people receive 500 mg of vitamin C intramuscularly

Category

Treatment - Drugs

2

Description

Intervention group2: 50 people receive 100 iu of vitamin E intramuscularly

Category

Treatment - Drugs

3

Description

Intervention group3: 50 people receive 100 iu of vitamin E and 500 mg vit C intramuscularly

Category

Treatment - Drugs

4

Description

Control group: 50 people receive distilled muscle water

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiatallah hospital

Full name of responsible person

Benyamin Seyfari

Street address

Tehran . Gheytariyeh South .Jahantab St. Goche Biglerpour West . No. 28 .Unit 10

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2

Recruitment center

Name of recruitment center

Beheshti hospital Of Kashan

Full name of responsible person

Benyamin Seyfari

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Tehran .Gheytariyeh South . Jahantab St. Goche Biglerpour West . No. 28 . Unit 10

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr masoud Khosh mohabbat

Street address

Tehran . Baghiatollah hospital

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Email

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Benyamin Seyfari

Position

General surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Person responsible for updating data

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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