Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

متغیر ها 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 cantusions 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 Bl00d 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
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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 . Baghiatolah haspital
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Province
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Postal code
1939883614
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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 updating data

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City
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Tehran
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۱۹۳۹۸۸۳۶۱۴
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Email
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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