

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

evaluation the effect of recombinant erythropoietin on Haft -e- Tir & Sina hospitals' multiple trauma patients' need to recurrent blood transfusion & noninvasive hemodynamic & laboratory parameters

Protocol summary

Summary

The goal of research is the evaluation of the effect of recombinant erythropoietin on recurrent blood transfusion -noninvasive hemodynamic & laboratory parameters in multiple trauma patients. Inclusion criterias are blood transfusion within 24 hour of entrance of patient to the hospitals ,patient age more than 18years,agreement of the patient , & having no other disease.Exclusion criterias are disagreement , and death of patient.Target sample size is 60 patients.The intervention is transfusion of 300u/kg erythropoietin intravenous together with blood transfusion within the first 24 hours of entrance of patients to the hospitals with aim to decrease the needs to recurrent blood transfusion & improvement of vital signs & laboratory parameters:Hpcidine & Micro-albumine to creatinin ratio

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100617891N4**

Registration date: **2014-12-09, 1393/09/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-09, 1393/09/18

Registrant information

Name

Nader Tavakoli

Name of organization / entity

Iran University Of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Research of Iran Medical University

Expected recruitment start date

2014-12-06, 1393/09/15

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation the effect of recombinant erythropoietin on Haft -e- Tir & Sina hospitals' multiple trauma patients' need to recurrent blood transfusion & noninvasive hemodynamic & laboratory parameters

Public title

evaluation the effect of erythropoietin on multiple trauma patients that need blood transfusion

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria:being Multiple Trauma, age more than18 years, blood transfusion within 24 hours of entrance to the hospital, consious agreement of the patient (if has ability to decide & is completely alert) or his legal attendant/ deputy(in other situations),no affection to other diseases exclusion criteria: consious disagreement of the patient or his legal attendant/

deputy during the research, death of patient within first three days of hospital admission

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

vice chancellor for research of Tehran medical science university

Street address

Keshavarz Boulevard corner of Ghods bystreet central organization of Tehran medical science university 6th floor

City

Tehran

Postal code

1417653761

Approval date

2014-09-28, 1393/07/06

Ethics committee reference number

1640 /130 /93/ ۵

Health conditions studied

1

Description of health condition studied

blood transfusion in multiple trauma patient

ICD-10 code

T79.2

ICD-10 code description

Traumatic secondary and recurrent haemorrhage

Primary outcomes

1

Description

blood transfusion volume to the patient

Timepoint

end of patient admission at the hospital

Method of measurement

number of pack cells with counting the documented transfused pack cells in patients' files

2

Description

blood pressure

Timepoint

at the beginning & third day of trial

Method of measurement

mm Hg with using mercury sphyngomanometer set

3

Description

heart beats

Timepoint

at the beginning & third day of trial

Method of measurement

number of heart beats per minute with using heart monitoring set

4

Description

blood oxygen saturation

Timepoint

at the beginning & third day of trial

Method of measurement

percent of blood oxygen saturation with using pulse oximeter set

5

Description

respiratory rate

Timepoint

at the beginning & third day of trial

Method of measurement

number of patient's breath per minute with physical examination

6

Description

plasma hepcidin

Timepoint

third day of trial

Method of measurement

nanogram per mililiter with using elisa technique

7

Description

urine microalbumine to creatinine ratio

Timepoint

third day of trial

Method of measurement

miligram on milimoll with using radiimmunoassay & Jaffe techniques respectively

Secondary outcomes

1

Description

stay length of patient in hospital

Timepoint

end of patient's admission in hospital

Method of measurement

number of admission days of patient in hospital with using formula discharge date minus admission date plus one

2

Description

patient's hotelling price in hospital

Timepoint

end of patient's admission in hospital

Method of measurement

price documented in patient's economic file in Rials

Intervention groups

1

Description

Intra venous transfusion of recombinant erythropoitin as 300 unit per Kg of patient's weight in two minutes duration slowly under cardiac & respiratory monitoring in intervention group as a single dose together with blood transfusion in first day of hospital admission of patient in hospital

Category

Treatment - Drugs

2

Description

would not be done in control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Haftom -e-Tir Shahre Ray

Full name of responsible person

Ali Mannani

Street address

south Shahid Rajae Highway

City

Tehran

2

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Ali Mannani

Street address

Hasan Abad square , Emam Khomeini street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research

Full name of responsible person

Seyed Ali Javad Moosavi

Street address

Chamran Highway , enterance of Hemmat Highway , besides the Milad tower , Iran University of Medical Science

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Ali Mannani

Position

resident of emergency medicine

Other areas of specialty/work

Street address

Shohadaye Haftom -e- Tir hospital , Emergency ward

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*