

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of plasmapheresis on respiratory condition and acidosis of patients with unstable complex pelvic fracture and long bones

Protocol summary

Summary

Now a day traumas are one of the most challenging fields in medicine. About 90% of severe traumas are accompanied by bone fractures. The main reason of mortality in blunt severe traumas is multiple organ failure, which is caused by the inflammatory response following trauma. Main acts of this inflammatory response are modified by Tumor necrosis factor α , Interleukin 1 β and Interleukin 6. Plasmapheresis a method in which inflammatory mediators and auto-antibodies are extracted from blood. In this study it will be tried to assess effect of plasmapheresis on respiratory status and acidosis as a part of recovery process. In this clinical trial 12 patients with complex instable hip or long bone fracture who will attend Emergency department of Emam Reza medical-educational center (Tabriz, Iran) and will be admitted to intense care unit, will be included in study. Included patients will undergo Plasmapheresis and its effect on respiratory status and acidosis will be examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082718946N1**

Registration date: **2014-10-03, 1393/07/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-03, 1393/07/11

Registrant information

Name

Reza Piri

Name of organization / entity

Emam Reza educational-medical center, Tabriz
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 5372

Email address

reza.piri@rocketmail.com

Recruitment status

Recruitment complete

Funding source

Tabriz University of medical sciences

Expected recruitment start date

2014-10-01, 1393/07/09

Expected recruitment end date

2015-10-01, 1394/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of plasmapheresis on respiratory condition and acidosis of patients with unstable complex pelvic fracture and long bones

Public title

Effects of plasmapheresis on patients with unstable complex pelvic fracture and long bones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 15 and 65 years old; having unstable complex hip or long bone fracture; being admitted to Intense care unit; being tachypneic; suffering respiratory distress; having low oxygen saturation; having Acidosis. Exclusion criteria: having renal failure history; Glasgow coma score less than 8 at

time of hospitalization; having angioplasty history; having history of chronic respiratory disease (e.g. Asthma, chronic obstructive pulmonary disease,...); concomitant renal, hepatic, cardiac or central nervous system injury in recent trauma; unstable hemodynamic; requiring surgical intervention.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Central campus of Tabriz University of Medical Sciences, Golgasht street, Azadi avenue.

City

Tabriz

Postal code

Approval date

2014-09-01, 1393/06/10

Ethics committee reference number

9397

Health conditions studied

1

Description of health condition studied

Unstable complex fracture of pelvic or long bones.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Respiratory rate

Timepoint

Daily and 2 hours after intervention.

Method of measurement

Counting by physician

2

Description

Respiratory distress

Timepoint

Daily and 2 hours after intervention.

Method of measurement

Examination by physician.

Secondary outcomes

1

Description

Arterial blood gas.

Timepoint

Daily and 2 hours after intervention.

Method of measurement

Arterial blood gases laboratory.

Intervention groups

1

Description

Intervention group: Patients with unstable complex fracture of hip and long bones, who are admitted to intense care unit, will be examined to assess their respiratory status (Arterial blood gas, respiratory rate and respiratory distress) every day 6 am. Patients will undergo plasmapheresis after acquiring mentioned parameters. Two hours after plasmapheresis, patients will undergo mentioned examinations again. Patients will undergo plasmapheresis every 24 hours until their condition has not changed or their hemodynamic status has not deteriorated.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza medical-educational centre, Tarbiz University of Medical Sciences

Full name of responsible person

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Central campus of Tabriz University of Medical Sciences, Golgasht street, Azadi avenue.

City

Tabriz

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, Tabriz University of Medical Sciences

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

Emam Reza educational-medical center

Full name of responsible person

Dr. Ramin Azhough

Position

Assistant professor of general surgery

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Ali Shahavand

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MD, general surgery resident

Other areas of specialty/work

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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