Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of intravenous Acetylcysteine effects on the Plasma concentration of α –Defensin and Gluthation in mechanically ventilated critically traumatic patients.

Protocol summary

Summary

The study goal is to evaluate the effect of N-Acetylcysteine on the prevention of oxidative stress and immune suppression in critically traumatic patients on mechanical ventilation. Adult patients with ICU admission following trauma are included in the study and patients with renal, hepatic and cardiac dysfunction will be excluded. A total 44 patients will be randomized in the intervention and control groups. The intervention is 3 grams of intravenous N-Acetylcysteine every 6 hours for 72 hours. The effects on length of ICU stay, one month mortality, length of mechanical ventilation dependence, risk of multi-organ damage and changes in serum markers of defensin and IgM as immune system indicators and glutathione as oxidative stress indicator will be compared with control group which only receives routine therapies.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010716120N1**
Registration date: **2014-02-23, 1392/12/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-23, 1392/12/04

Registrant information

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Name of organization / entity

TUMS

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tehran University of Medical Sciences

Expected recruitment start date

2014-01-30, 1392/11/10

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of intravenous Acetylcysteine effects on the Plasma concentration of α –Defensin and Gluthation in mechanically ventilated critically traumatic patients.

Public title

The effect of Acetylcysteine on prevention of oxidative stress and immunosuppression in the mechanically ventilated critically traumatic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ICU admission fallowing trauma; need for mechanical ventilation ; FiO2 more than 50% ; At least two Systemic Inflammatory Response(SIRS) criteria (Body temperature more than 38°C or less than 36°C, Heart rate more than 90 beats/min, Respiratory rate

more than 20 breath/min or PaCo2 less than 32 mm Hg, WBC more than 12,000 cells/mm3, or less than 4000 cells/mm3, or more than 10% immature (band) cells) Exclusion criteria:Age lower than 18 ; Acute Physiology and Chronic Health Evaluation(APACHE) II score lower than 15 ; Central Venous Pressure (CVP) > 18 mmHg ; Systolic Blood Pressure < 90 mmHg or Mean Arterial Pressure (MAP) < 60 mmHg ; Serum Creatinine ≥ 2 mg/dl; urine output less than 0.5 ml/Kg/hour; liver dysfunction (defined as the presence of hepatic cirrhosis or concentration of serum trans-aminases greater than third times the upper limit of normal range) ; history of myocardial infarction or heart failure (EF< 40%) and those received N-acetyl Cysteine (NAC) before initiation of study were excluded from the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 University of Medical Sciences

Street address
Ghods St., Keshavarz Crossroad

City
Tehran

Postal code

Approval date
2009-09-23, 1388/07/01

Ethics committee reference number
88-01-33-8503

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
Immunoglobulin M

Timepoint
baseline, day 1, day 3 and day 5

Method of measurement
laboratory study

2

Description
Glutathione

Timepoint
baseline, day 1, day 3 and day 5

Method of measurement
laboratory study

3

Description
human β-defensin 2

Timepoint
baseline, day 1, day 3 and day 5

Method of measurement
laboratory study

Secondary outcomes

1

Description
SOFA score

Timepoint
baseline, days 1,2,3,4 and 5

Method of measurement
standard chart

2

Description
WBC

Timepoint
baseline, days 1,2,3,4 and 5

Method of measurement
laboratory study

3

Description
Absolute neutrophil count

Timepoint

baseline, days 1,2,3,4 and 5

Method of measurement

laboratory study

Intervention groups

1

Description

3 grams of NAC every 6 hours with slow intravenous infusion for 72 hours

Category

Treatment - Drugs

2

Description

No specific intervention in control group other than routine treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

General ICU of Sina hospital

Full name of responsible person

Professor Mojtaba Mojtahedzadeh

Street address

Imam khomeyni St., Before Hasan-abad Sq.

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tehran University of Medical Sciences

Full name of responsible person

Mrs. Saeedi

Street address

Pursina St.

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 of Tehran 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

Pharmaceutical Sciences Research Center of the Tehran University of Medical Sciences

Full name of responsible person

professor Mojtaba Mojtahedzadeh

Position

full professor in clinical pharmacy

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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