

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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

Name

Farhad Najmeddin

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 following 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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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.

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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

Other areas of specialty/work

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Person responsible for updating data

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Clinical pharmacy specialist

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