Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation the effect of defrasirox on inflammatory biomarkers in broncgoalveolar lavage fluid of mechnically ventilated patients

Protocol summary

Summary
The general goal of study is improvement in tolerance of oxygenation by reduction of one of the marker of oxidative stress. 20 mechanically ventilated mechanically ventilated critically ill patients who undergo mechanical ventilation for 3 days with 50% Fio2 and have as stable hemodynamic and acceptable vital organ function are enrolled and receive deferasirox 1500 mg for 3 days. the primary outcome of study are oxidative stress markers and iron-related factor , mortality rate and organ function that will be assessed by APACHE 2 and SOFA respectively.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT138709181497N1**
Registration date: **2010-03-21, 1389/01/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2010-03-21, 1389/01/01

Registrant information
Name
Sarah Mousavi
Name of organization / entity
Clinical Pharmacy Department, Pharmacy Faculty, Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3792 2567
Email address
smousavi@razi.tums.ac.ir

Recruitment status
Recruitment complete
Funding source
Pharmaceutical Sciences Research Center of pharmacy faculty of Tehran University of Medical Sciences and Health services

Expected recruitment start date
2009-03-11, 1387/12/21
Expected recruitment end date
2010-05-01, 1389/02/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation the effect of defrasirox on inflammatory biomarkers in broncgoalveolar lavage fluid of mechnically ventilated patients

Public title
Role of iron chelator in oxidative stress
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Mechanically ventilated patients, Fio2 more than 50% for at least 3 days and PEEP equal to 5, Ability to receive drug by oral route Exclusion criteria: Dissatisfaction of patients or family, other diseases that cause pulmonary edema such as CHF, pulmonary hemorrhage, age less than 18, patients who are NPO, severe liver failure (ALT, AST>5 times of baseline), moderate to severe renal failure (Cr >1mg/dl or u/o <0.5cc/kg/hr or dialysis), patients who are in shock (PH <7.2 , Pao2/Fio2 <100 , MAP< 65), receiving other anti-inflammatory drugs such as NAC or corticosteroids, history of leukemia, BMT, thalassemia, iron deficiency anemia, receiving iron chelator drugs during 3 months

prior to the study, receiving chemotherapy or immunosuppressive drugs during 3 months prior to the study, Level of ferritin less than 30 mcg/L, Grade 2-3 of heart block, QT prolongation, positive viral markers such as HIV, HBV , HCV, WBC<3000, ANC<1500, PLT<50000, Ejection Fraction <55%

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

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
Tehran University of Medical Sciences and Health Services associated ethics committee

Street address
6th floor,central organisation of tums,ghods Ave, keshavarz Blvd

City
Tehran

Postal code

Approval date
2009-02-10, 1387/11/22

Ethics committee reference number
970/130/ص

Health conditions studied

1

Description of health condition studied
critically ill mechanically ventilated patients

ICD-10 code
J96.9

ICD-10 code description
Respiratory failure, unspecified

Primary outcomes

1

Description
8-isoprostane in plasma and BAL fluid

Timepoint
0 and 72 hour after drug administration

Method of measurement
human elisa kit

2

Description
carbonyl protein in plasma and BAL fluid

Timepoint
0 and 72 hour after drug

Method of measurement
human elisa kit

3

Description
8-oxoguanin in plasma and BAL fluid

Timepoint
0 and 72 hour after drug

Method of measurement
human elisa kit

4

Description
ferritin in plasma and BAL fluid

Timepoint
0 and 72 hour after drug

Method of measurement
human elisa kit

5

Description
transferrin in plasma and BAL fluid

Timepoint
0 and 72 hour after drug

Method of measurement
human elisa kit

6

Description
free iron in plasma and BAL fluid

Timepoint
0 and 72 hour after drug

Method of measurement
spectroscopy method

Secondary outcomes

1

Description
mortality rate

Timepoint

from the time of treatment until 1 week

Method of measurement

APACHE2

2

Description

Assesment of organ failure

Timepoint

from the time of treatment until 1 week

Method of measurement

SOFA

Intervention groups

1

Description

Deferasirox 1500 mg(po) for 3 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

general intensive care unit of sina teaching hospital affilated to Tehran University Of Medical Scie

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmaceutical Science Research Center of Pharmacy Faculty of Tehran University Of Medical Sciences

Full name of responsible person

Dr Mohammad Abdollahi

Street address

3rd floor, old building, pharmacy faculty, 16 azar Ave, Keshavarz Blvd,

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharmaceutical Science Research Center of Pharmacy Faculty 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Toxicology department ,Pharmacy Faculty,Tehran University Of Medical Sciences and Health Services

Full name of responsible person

Dr Mojtaba Mojtahedzadeh

Position

Professor

Other areas of specialty/work

Street address

2nd floor, old building, pharmacy faculty, 16 azar Ave, keshavarz Blvd, pharmacotherapy dep.

City

Tehran

Postal code

Phone

+98 21 6412 2208

Fax

Email

mojtahed@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Pharmacotherapy resident,Pharmacy faculty,Tehran University Of Medical Sciences and Health Services

Full name of responsible person

Dr Sarah Mousavi

Position

Resident of pharmacotherapy

Other areas of specialty/work

Street address

2nd floor, old building, pharmacy faculty, 16 azar Ave, keshavarz Blvd, pharmacotherapy dep.

City

Tehran

Postal code

1439957181

Phone

+98 21 6412 2208

Fax

Email

smousavi@razi.tums.ac.ir

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