

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of autologous adipose mesenchymal stem cells in treatment of airway injury in patients exposed to sulfur mustard

Protocol summary

Summary

The aim of research: Changes in morphological structure of airway system are associated with chronic obstructive pulmonary deficiency following exposure to sulfur mustard gas. With extensive progress and achievements in tissue repairing through stem cells therapy, considering of lung tissue has been increased due to the high prevalence of pulmonary problems. Several factors such as selection of cell types, necessary conditions for growth and proliferation of stem cells, and the process of entering into the body to repair of damaged lung tissue are considered as the most important problems in this issue. Use of mesenchymal stem cells (MSC) in animals and human clinical trials supported the hypothesis of therapeutic effects of these cells in various disorders. The aim of this study is to evaluate MSC safety and perform an initial evaluation of the potential efficacy of systemic MSC administration to sulfur mustard patients with chronic lung injuries. Methods: Ten patients will receive 100 million cells per each infusion for two months and then they will be followed for 6 month after the first infusion. Finally, patients will be considered in case of safety of treatment, pulmonary function testing (PFT), quality-of-life indicators, 6MWT, and expression of inflammation and oxidative stress genes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110524890N1**

Registration date: **2015-11-25, 1394/09/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-25, 1394/09/04

Registrant information

Name

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Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Veterans Foundation

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of autologous adipose mesenchymal stem cells in treatment of airway injury in patients exposed to sulfur mustard

Public title

Use of stem cells in treatment of lung injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who had a documentary exposure to mustard gas in the Iran-Iraq war; their disease severity were as following based on spirometric: moderate $50 < FEV1 < 65$ or severe $40 < FEV1 < 50$; absence

of contraindications spirometry (recent MI ,hemoptysis, cerebral arterial aneurysm or aortic, pulmonary embolism, uncontrolled blood pressure, recent pneumothorax, no doubt surgery/recent thoracic, recent eye surgery, recent stroke); non-availability in another research study at a same time; no coagulation disorders; exclusion criteria: smoking; the incidence of pneumonia during the study; the incidence of transfusion reaction; other medical condition (cardiovascular disease, hypertension, diabetes); visiting less than 2 times.

Age

From **54 years** old to **34 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

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

Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences

City

Tehran

Postal code

Approval date

2014-05-31, 1393/03/10

Ethics committee reference number

IR.BMSU.REC.1393.32

Health conditions studied

1

Description of health condition studied

Airway damage in chemical injuries

ICD-10 code

J68.4

ICD-10 code description

Chronic respiratory conditions due to chemicals, gases, fumes and vapours

Primary outcomes

1

Description

Improvement in breathing and respiratory capacity

Timepoint

2 month

Method of measurement

spirometry test, kit, molecular assay

Secondary outcomes

1

Description

Treatment of damaged airway

Timepoint

1 years

Method of measurement

spirometry test and kit

Intervention groups

1

Description

Patients will receive 100 millions cells during 4 injections for a period of two month.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Amir Nejadmoghaddam

Street address

Baqiyatallah Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Veterans Foundation

Full name of responsible person

Dr Sedighi Moghaddam

Street address

Taleghani Street, between Hafez and Vali-Asr

City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Veterans Foundation
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

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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