

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of two stem cells utilization methods; intravenous and intra alveolar injection by bronchoscopy on outcome of severe lung contusion in patients admitted to intensive care unit (ICU)

Protocol summary

Study aim

A comparison of two stem cells utilization methods including intravenous and intra-alveolar infiltration on outcome of severe lung contusion in patients admitted to intensive care unit (ICU)

Design

A clinical trial with a control group and two intervention groups, with parallel groups, single-blind, randomized, phase 2 on 30 patients. R statistical software is used for block randomization.

Settings and conduct

This clinical trial, is performed on 30 patients with severe hypoxia requiring mechanical ventilation and admitted to the ICU during the first 24 hours at Shahid Bahonar Hospital, Kerman. It is a single-blind study, so that the results are determined by uninformed anesthesiologist, nurse, and laboratory personnel.

Participants/Inclusion and exclusion criteria

Inclusion criteria: arterial oxygen pressure to inspiratory oxygen less than 180; bilateral infiltration with pulmonary edema; pulmonary contusion more than 40%; need to ICU admission; age between 18 and 65 years. Non-inclusion criteria: pregnant or lactating women; active malignancy; mortality probability more than 50% in the next six months; moderate to severe liver disorder; severe chronic lung disease; lung transplant

Intervention groups

Intervention group 1: will be injected with 60 million dental pulp stem cells intravenously; Intervention group 2: will be pushed dental pulp stem cells inside the Alveolus by bronchoscope; Intervention group 3: will only receive the usual treatments.

Main outcome variables

Arterial to inspiratory oxygen pressure ratio; ventilation duration; death; length of ICU hospitalization; need for intubation; forced vital capacity(FVC); forced expiratory volume in one second to FVC

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101220005426N12**

Registration date: **2022-10-29, 1401/08/07**

Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**

Update count: **0**

Registration date

2022-10-29, 1401/08/07

Registrant information

Name

Mehdi Ahmadinejad

Name of organization / entity

Anesthesiology department, Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of two stem cells utilization methods; intravenous and intra alveolar injection by bronchoscopy on outcome of severe lung contusion in patients admitted to intensive care unit (ICU)

Public title

A comparison of two stem cells utilization methods; intravenous and intra alveolar injection by bronchoscope on outcome of severe lung contusion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The pressure of arterial oxygen to inspiratory oxygen should be less than 180(PaO2/FIO2<180) Bilateral infiltration with pulmonary edema in anterior lung radiography Pulmonary contusion greater than 40% in chest CT scan The need to transfer to the intensive care unit due to respiratory failure Criteria 1-4 must all be present within a 24-hour period at the time of study entry

Exclusion criteria:

More than 96 hours have passed since the patient's ARDS trauma Pregnant or lactating woman Presence of any active malignancy (other than nonmelanoma skin cancer) that requires treatment within 2 years Any irreversible disease such as malignancies and a condition with a 50% chance of death within the next six months Moderate to severe liver disorder based on Child-Puff criteria<12 chronic obstructive pulmonary disease(COPD) The patient has undergone a lung transplant The patient's lack of consent, or if the patient is unable to answer, the patient's guardian's lack of consent A patient who is not expected to be alive in the next 24 hours according to the Apache criteria Class III or IV pulmonary hypertension Pulmonary embolism or deep vein thrombosis in the past three months Brain trauma Transfusion of large volume of blood (injection of more than 10 units of blood in the last 24 hours) The presence of heart failure, kidney and diabetes Patients in a state of shock and previous concurrent contusion

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize people to three groups, the block randomization method is used in such a way that blocks

of size 6 are used. R statistical software is used for random block allocation

Blinding (investigator's opinion)

Single blinded

Blinding description

It is a one-way blind method in which stem cells are injected by an ICU specialist. Examination of pneumonia (CPIS criteria, clinical history, clinical examination and chest x-ray) will be done by an anesthesiologist, and the arterial oxygen pressure will be checked by the senior ICU nurse who does not know the type of cell injection to the patients. Also, laboratory tests will be done by a technician who's not aware of the interventions will be made

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee, Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jahad street

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7619813159

Approval date

2022-06-25, 1401/04/04

Ethics committee reference number

IR.KMU.REC.1401.128

Health conditions studied**1****Description of health condition studied**

lung contusion

ICD-10 code

S27.32

ICD-10 code description

Contusion of lung

Primary outcomes**1****Description**

Arterial oxygen pressure to inspiratory oxygen pressure ratio

Timepoint

The ratio of arterial oxygen pressure to inspiratory oxygen pressure at the beginning of the study (before the start of the intervention) and 1, 4 and 10 days after cell injection in intervention and control groups

Method of measurement

ABG

2

Description

Average duration (days) of ventilation

Timepoint

After the intervention, daily until the end of hospitalization

Method of measurement

check list

3

Description

death

Timepoint

death between 28 and 60 days after the start of the study

Method of measurement

Check list

4

Description

Average period of stay in ICU

Timepoint

The average period of stay in the ICU between 28 and 60 days after the start of the study in the intervention and control groups

Method of measurement

check list

5

Description

Need for intubation

Timepoint

Need for intubation during the study

Method of measurement

Check list

6

Description

forced expiratory volume in the first one second to the forced vital capacity(FEV1/FVC)

Timepoint

forced expiratory volume in the first one second to the forced vital capacity(FEV1/FVC) at the 1, 3 and 6 months after the start of study in intervention and control groups

Method of measurement

spirometry

7

Description

Forced vital capacity

Timepoint

Forced vital capacity at the 1, 3 and 6 months after the start of study in intervention and control groups

Method of measurement

spirometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The first group will receive 60 million dental pulp stem cells intravenously in addition to common supportive treatments

Category

Treatment - Other

2

Description

Intervention group 2: The second group, in addition to common supportive treatments, 60 million dental pulp stem cells are pushed by a bronchoscope inside the lung alveoli in the contusion area (based on CT scan findings).

Category

Treatment - Other

3

Description

Control group: They will only be treated by usual treatments

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital, Kerman

Full name of responsible person

Mehdi Ahmadinejad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ahmadinejad

Position

Assistant Professor- Fellow of Intensive Care

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available