

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Sep 2021

using Human decidua stromal cells for the treatment of acute respiratory distress syndrome (ARDS), Phase 2

Protocol summary

Summary

This study is the second phase of a RCT study that attempts to employ the stem cells isolated from the embryonic membranes as a strategy for treatment of patients with acute respiratory distress syndrome. To achieve this goal, three groups (each group includes 5 cases) suffering from acute respiratory syndrome referred to two hospitals in Tehran (Shariati and Imam Khomeini) will be selected. Inclusion criterion is patients with age >18. On the other hand, exclusion criterion would be any acute and systemic infections like HIV, Hepatitis B and C. The first, second, and third groups will intravenously receive 1000000/kg, 2000000/kg, and 5000000/kg embryonic stromal cells, respectively (each injection should take 30 minutes). Patients will be monitored by ICU specialists for possible complications immediately after injections. Indeed, the major complication in this study is expected to be the elevation in patient's doses of vasopressors (norepinephrine, phenylepinephrine, dopamine, epinephrine, etc.) Other complications are post-injection clinical instabilities especially in cardiac and respiratory systems, together with dose-limiting toxicity. It should be mentioned that no blinding will be utilized for evaluation of these complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010531786N1**

Registration date: **2017-03-27, 1396/01/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-27, 1396/01/07

Registrant information

Name

Behnam Sadeghi

Name of organization / entity

Breast Cancer Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 88679402

Email address

bsadeghi@ibcrc.ir

Recruitment status

Recruitment complete

Funding source

Breast Cancer Research Center (BCRC) collaboration with: 1: Pasteur Institute of Iran 2: Center for AIDS Research 3: Shariati Hospital

Expected recruitment start date

2017-01-01, 1395/10/12

Expected recruitment end date

2019-01-01, 1397/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

using Human decidua stromal cells for the treatment of acute respiratory distress syndrome (ARDS), Phase 2

Public title

Isolation , Purification, Characterization and Commercialization of Stem Cells From Fetal Membrane layers and Their Use for the Treatment of Patients With Acute Respiratory Distress Syndrome (ARDS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients over 18 years of age; Diagnosis is done by Berlin definition; The disease is acute; Bilateral lungs with pulmonary edema are evident on X-ray; The patient does not have a history of heart failure; PaO₂ / FiO₂ less than 200 while the patient is under mechanical ventilation via endotracheal tube or tracheostomy tube with positive end-expiratory pressure at least 8 inches of water; A fungal infection does not exist. Exclusion criteria: If three days have passed from the onset of the disease; Any disease history of the vital organs such as heart disease, kidney or liver; Pregnancy; Pulmonary hypertension; Cancer; AIDS; seronegative for hepatitis A and B; seronegative for syphilis; Symptoms of pulmonary embolism.

Age

From **18 years** old to **99 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethnic Committee, Breast Cancer Research Center (BCRC), Motamed Cancer Institute, Tehran Un

Street address

No 146, Corner of Southern Gandhi Street, Vanak Square

City

Tehran

Postal code

Approval date

2016-08-14, 1395/05/24

Ethics committee reference number

IR.ACECR.IBCRC.REC.1395.13

Health conditions studied

1

Description of health condition studied

Acute Respiratory Distress Syndrome

ICD-10 code

J80

ICD-10 code description

Acute Respiratory Distress Syndrome

Primary outcomes

1

Description

dose of third vasopressor

Timepoint

6 hours after injection

Method of measurement

1-Norepinephrine: 10 µg per min 2- Phenylephrine: 100 µg per min 3- Dopamine: 10 µg / kg per min 4- Epinephrine: 0 - 1 µg / kg per min in serum

2

Description

Hypoxemia

Timepoint

6 hours after injection

Method of measurement

FiO₂ ≥0.2 or PEEP = 5 cmH₂O or more

3

Description

Occurrence cardiogenic cardiac or ventricular arrhythmia

Timepoint

6 hours after injection

Method of measurement

Clinical examination and electrocardiogram

Secondary outcomes

1

Description

Cardiac arrest or death

Timepoint

24 hours after injection

Method of measurement

Clinical Examination

2

Description

septicemia

Timepoint

6 hours after injection

Method of measurement

Base on urine and blood laboratory examination

3

Description

rapid clinical instability after injection in the cardiovascular and respiratory systems

Timepoint

30 min after injection

Method of measurement

Change in systolic or diastolic blood pressure, mean arterial blood pressure changes

4**Description**

drug toxicity

Timepoint

30 min after injection

Method of measurement

Pulmonary embolism, fever, respiratory inflammation

Intervention groups**1****Description**

In the first group of intervention; the intervention is the injection of 1 million stromal cells of embryonic membranes intravenously in 30 minutes.

Category

Treatment - Drugs

2**Description**

In the second group of intervention; the intervention is the injection of 2 million stromal cells of embryonic membranes intravenously in 30 minutes.

Category

Treatment - Drugs

3**Description**

In the third group of intervention; the intervention is the injection of 5 million stromal cells of embryonic membranes intravenously in 30 minutes.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital, Tehran University of Medical Sciences

Full name of responsible person

Behnam Sadeghi

Street address**City**

Tehran

2**Recruitment center****Name of recruitment center**

Shariati Hospital, Tehran University of Medical Sciences

Full name of responsible person

Behnam Sadeghi

Street address**City**

Tehran

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

Breast Cancer Research Center (BCRC), Motamed Cancer Institute, Tehran University of Medical science

Full name of responsible person

Behnam Sadeghi

Street address

No 146, Corner of Southern Gandhi Street, Vanak Square

City

Tehran

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

Yes

Title of funding source

Breast Cancer Research Center (BCRC), Motamed Cancer Institute, Tehran University of Medical science

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**

Breast Cancer Research Center (BCRC), Motamed Cancer Institute, Tehran University of Medical Science

Full name of responsible person

Behnam Sadeghi

Position

Assistant Professor of Immunology & Cell Therapy

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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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