Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2020

Effect of stromal vascular fraction (SVF), blood and condition medium derived exosomes on treatment of covid-19 patients with Acute Respiratory Distress Syndrome(ARDS)/ clinical Trial

Protocol summary

Study aim

The aim of this study was the efficacy of stromal vascular fractions, and also their conditioned media exosomes and blood exosomes in patients with covid-19 with acute respiratory distress syndrome /clinical trial in quality.

Design

This study is a multicenter, random, double-blind study in which patients with admission criteria will enter the study after obtaining conscious consent from themselves or legal guardians (this study will be conducted after the approval of the Ethics Committee of Tabriz University of Medical Sciences).

Settings and conduct

Subcutaneous fat is processed by the SVF separator(Lipogems), and will be purchased as a ready-made kit. Blood exosomes will also be isolated by ultracentrifuge. The conditioned medium obtained from SVF culture is collected to separate the exosome, after 6-8 hours three types of environment and autologous ready for injecton. These solutions are delivered in 3 consecutive days by delivering a volume of 10 ml through the trachea will be injected into the patient's lungs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Covid19 patients aged 15-70 years hospitalized in the ICU, which includes all confirmatory tests Satisfaction in studying Exlusion criteria: History of kidney transplantation History surgery on the lungs The presence of any malignancy Previous active infection Use immunosuppressive and other drugs The presence of autoimmune disease

Intervention groups

Patients will be divided in four control and experimental groups(60 patients: in each group of 15 patients). Routine control group with routine treatment Autologous SVF receiving group Autologous blood exosome group SVF Autologous Fluid Exposure Group It should be noted that all groups receive the same common treatments.

Main outcome variables

SOFA score Lung damage score on days 0, 4, 7, 14a assess inflammatory status (IL1, IL6) Oxidative Status (TAC)

General information

Reason for update

Acronym

تاثیرقطعه عروقی استروما و اگزوزوم دربیماران کووید 19مبتلا به سندرم دیسترس تنفسی حاد

IRCT registration information

IRCT registration number: **IRCT20200510047385N1**
Registration date: **2020-07-07, 1399/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-07, 1399/04/17**
Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Leila Roshangar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 3870

Email address

lroshangar@yahoo.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date
2021-03-10, 1399/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of stromal vascular fraction (SVF), blood and condition medium derived exosomes on treatment of covid-19 patients with Acute Respiratory Distress Syndrome(ARDS)/ clinical Trial

Public title
Effects of SVF and exosome in covid-19 patients with acute respiratory distress syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
covid19 patients hospitalized in the ICU, which includes all confirmatory tests – Satisfaction in studying
Exclusion criteria:
History of kidney transplantation History surgery on the lungs The presence of any malignancy Previous active infection Use immunosuppressive and other drugs The presence of autoimmune disease
Age
From **15 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants are leading researchers, especially in trials initiated by academic researchers, health care personnel (physicians, nurses, etc.) who are responsible for patient care, data collection authorities and those Assessing the outcome will be blind. The Data Safety and Monitoring Committee will not be blind. To receive blood samples from patients, the relevant code of ethics will be obtained from the Ethics Committee of Tabriz University of Medical Sciences. In addition, patients will be given informed consent to participate in the study. This study has no cost for patients and patients can leave the study at any time. All patient information will be confidential.
Placebo
Not used
Assignment
Factorial
Other design features
Due to the fact that the approved kit for Svf separation will be used it is processed non-enzymatically and for a maximum of 2 hours and will be autologous and we will not have cell culture and will be done in the operating room, all the rules related to GCP, GMP will be considered

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of tabriz University of Medical Sciencesدانشگاه
Street address
no7, baghshomal ave, banafshe, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138664393
Approval date
2020-07-01, 1399/04/11
Ethics committee reference number
1399.095.IR.TBZMED.VCR.REC

Health conditions studied

1

Description of health condition studied
Covid19
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Evaluation of inflammatory status IL1,
Timepoint
per 3 days
Method of measurement
Eliza

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients are divided into four control and experimental groups (60 patients: 15 patients in each group). Routine control group with routine treatment Receiver group SVF autologous group Blood exosome group Autologous group exposed to SVF autologous fluid It should be noted that all groups receive the same common treatments

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospital

Full name of responsible person
Dr ata mahmoodpor

Street address
Attat ave, emam reza hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
mohammad samiei

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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
Tabriz University of Medical Sciences

Proportion provided by this source
40

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
Tabriz University of Medical Sciences

Full name of responsible person
leila Roshangar

Position
Academic member

Latest degree
Ph.D.

Other areas of specialty/work
Histology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data will be published in the form of an article

When the data will become available and for how long
2 year

To whom data/document is available
All

Under which criteria data/document could be used
Awareness and no conditions

From where data/document is obtainable
Article or email

What processes are involved for a request to access data/document
email

Comments