

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigation the effect of relaxtation on miR-21 expression and serum levels of IL-10 and IFN-γ in patients infected with COVID-19

Protocol summary

Study aim

Determination of serum levels of IFN-γ, IL-10 and miR-21 in patients with COVID-19 before and after relaxation intervention

Design

Using the available sampling method, the sample size is calculated and the serum level of the factors is measured before and after the intervention.

Settings and conduct

In this study, a sedative audio file will be played for patients with COVID-19 admitted to Ali-ebn-Abi Talib Hospital of Rafsanjan. Blood samples were taken from patients before and after the intervention and serum levels of IFN-γ, IL-10 and mir-21 Will be measured.

Participants/Inclusion and exclusion criteria

Patiant's whose disease have been confirmed in terms of clinical findings and CT scan findings as well as RT-PCR test by a specialist and are under 80 years of age and their blood oxygen saturation is below 93% are selected for the study. Pregnant and lactating women will not be included in the study.

Intervention groups

In this study, a sedative audio file will be played for patients with COVID-19 and its effectiveness will be measured.

Main outcome variables

The main purpose of this study was to reduce stress in patients with COVID-19 using a sedative audio file and measuring serum levels of IFN-γ, IL-10 and mir-21. If this sedative audio file is effective, sedative audio files can be used to reduce patients' stress and help them to recover.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210413050959N1**

Registration date: **2021-08-17, 1400/05/26**

Registration timing: **prospective**

Last update: **2021-08-17, 1400/05/26**

Update count: **0**

Registration date

2021-08-17, 1400/05/26

Registrant information

Name

Fatemeh Amin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0041

Email address

dramin@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of relaxtation on miR-21 expression and serum levels of IL-10 and IFN-γ in patients infected with COVID-19

Public title

Investigation the effect of relaxtation on miR-21

expression and serum levels of IL-10 and IFN- γ in patients infected with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients whose disease have been confirmed in terms of clinical findings and CT scan findings as well as RT-PCR test by a specialist Confirmation of pneumonia by chest x-ray Blood oxygen saturation below 93% Relative stability of cardiovascular status
Exclusion criteria:
Disapproval of RT-PCR test Dissatisfaction of patients The opinion of the treating physician to exclude the patient from the study Decreased blood oxygen saturation below 85% while using a ventilator or nasal passage People with underlying diseases

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

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

Ethics committee of Rafsanjan University

Street address

Imam Ali Boulevard - Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

771793777

Approval date

2021-07-28, 1400/05/06

Ethics committee reference number

IR.RUMS.REC.1399.211

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum levels of IL-10, MIR-21 and IFN- γ and patients' stress scores are measured before and after the intervention (listening to the audio file).

Timepoint

Serum levels of IL-10, MIR-21 and IFN- γ are measured before the intervention and 5 to 6 days after the intervention (listening to the audio file).

Method of measurement

Patients' stress levels and serum levels of IL-10, MIR-21 and IFN- γ F are measured using questionnaire and ELISA technique respectively.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients who listen to sedative audio file.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ebn-Abi Talib Hospital of Rafsanjan

Full name of responsible person

Fatemeh Amin

Street address

Imam Ali Boulevard - Rafsanjan University of Medical Sciences

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Fatemeh Amin

Street address

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Fatemeh Amin

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Not applicable

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