Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Patiants 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:

Patiants 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 patiants 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

۷۷۱۷۹۳۳۷۷۷

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: patiants 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

ft.amin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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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 updating data

Contact

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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