

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of aqueous extract of violet on fever in patient with covid-19

Protocol summary

Study aim

Evaluation of the effect of aqueous extract of violet on fever in patient with covid-19

Design

A clinical trial with a control group, with parallel group, one-sided blind,, randomized, phase 1 on 52 patients, was used for randomization of blocking and envelope.

Settings and conduct

Febrile COVID-19 patients in Imam Khomeini Hospital of Amol who used violet syrup in the treatment of fever. The only statistical consultant in the statistical analysis process will be blinded..

Participants/Inclusion and exclusion criteria

Willingness to participate in the study, confirming covid-19 with positive PCR; Temperatures between 38.3°C and 40°C, patient's complete consciousness, lack of allergy to herbal medicines, Not receiving and not using other methods of reducing fever in 4 hours ago, not pregnant, and having no history of surgery or head trauma, Seizure

Intervention groups

Control group, including received Ampoules 1 gram acetaminophen ampoule by intravenous infusion for 15 minutes and recording The temperature is 30 and 60 minutes and the end is 4 hours. Will receive. In the test group After recording the temperature, and receiving one gram acetaminophen injection by intravenous infusion for 15 minutes. 5 cc of Barij violet syrup will be used, then the temperature will be recorded at 30 and 60 minutes and at the end of 4 hours. For up to three days, follow-up and violet syrup will be given to patients every 8 hours and the patient's temperature will be recorded every 6 hours. In case of recurrence, acetaminophen injections will be repeated in both groups.

Main outcome variables

Fever

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150916024047N6**

Registration date: **2022-04-16, 1401/01/27**

Registration timing: **retrospective**

Last update: **2022-04-16, 1401/01/27**

Update count: **0**

Registration date

2022-04-16, 1401/01/27

Registrant information

Name

Hedayat Jafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3311 7268

Email address

hjafari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of aqueous extract of violet on fever in patient with covid-19

Public title

Evaluation of the effect extract of violet on fever patient with covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of covid 19 with positive PCR Temperature between 38.3 to 40 ° C Having a fever from the time of admission to 10 days Complete patient consciousness Lack of any sensitivity to herbal medicines, Not receiving and not using Other help methods to reduce fever in 4 hours before

Exclusion criteria:

Sensitivity to violet syrup Unwillingness to cooperate Not being pregnant Seizures History of head trauma and brain tumor and history of brain surgery due to possible hypothalamus disorders

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 52 patients were selected by convenience sampling method and were randomly assigned to one of the two experimental groups (A) and control (B). According to the 6 possible modes of placing letters in quadruple blocks, these blocks are numbered with numbers from one to six (AABB1- ABBA2 - BABA3 - BBAA4 -ABAB5 ABAB6) then using Random Allocation Software 2.0 one of the numbers up to Six are randomly selected for 13 times. The four blocks are placed in 13 opaque numbered envelopes according to a random selection sequence, and these envelopes are sealed by a person outside the research team, respectively, and the patients are assigned to the relevant groups.

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

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Faculty of Nursing, Midwifery., Vesal., Amir Mazandarani Stree., Sari t

City

Sari

Province

Mazandaran

Postal code

7815733971

Approval date

2021-06-16, 1400/03/26

Ethics committee reference number

IR.MAZUMS..REC.1400.8499

Health conditions studied

1

Description of health condition studied

COVID-19 Patients

ICD-10 code

U07.1

ICD-10 code description

COVID19, virus identified

Primary outcomes

1

Description

Fever

Timepoint

Q6h - 3day

Method of measurement

Before the intervention, patients' temperature is recorded with MICROLAB digital thermometer.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the experimental group, after recording the temperature and receiving acetaminophen ampoules, one gram intravenous infusion for 15 minutes and using 5 cc of violets barij extract prepared from the blue extract of Violets flower) with Product registration code no. 6599807159453166 from Bari j Essence Company, in people whose sweetness of syrup stimulates the throat due to red sugar, they can take the

dose in half of the water supply. Lukewarm dissolves and drinks slowly will be used. Temperatures will be recorded at 30, 60 minutes and the end of 4 hours. The patients' falloff will continue for three days and in case of fever in the experimental group, in addition to acetaminophen injection, violet syrup will be given to patients every 8 hours up to three days and the patient's temperature will be recorded every 6 hours and in case of no fever, violet syrup will be discontinued.

Category

Treatment - Drugs

2**Description**

The control group will receive routine measures including receiving 1g acetaminophen injection as intravenous infusion at 100 cc normal saline for 15 minutes. Follow-up will continue for up to 3 days and the patient's temperature will be recorded every 6 hours.

Category

Treatment - Drugs

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

Hazbital emam khomani amol

Full name of responsible person

khadijeh omranifar

Street address

Haraz

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4615747845

Phone

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Email

mahsaomranifar@gmail.com

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

Mazandaran University of Medical Sciences

Full name of responsible person

dr.hedayat. jafary

Street address

Nasibeh School of Nursing and Midwifery, vesal, amir mazandarani

City

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Province

Mazandaran

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4815733971

Phone

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Email

hedayat2003@yahoo.com

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

Yes

Title of funding source

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

DR.H. jafary

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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009833350602

Email

hedayat2003@yahoo.com

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

Mazandaran University of Medical Sciences

Full name of responsible person

dr.Hedayat.jafari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient name information will be kept confidential

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

Undecided - It is not yet known if there will be 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

If the names of the people are not identifiable - and only the main consequences

When the data will become available and for how long

After the end of the study

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

For researchers working in academic and scientific institutions

From where data/document is obtainable

mahsaomranifar@gmail.com

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

Confirmed by email from Academic Centers

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

Mazandaran University of Medical Sciences

Full name of responsible person

khadijeh omranifar

Position

Master student of intensive care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Province

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4615747845

Phone