

# 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

**City**

Amol

**Province**

Mazandaran

**Postal code**

4615747845

**Phone**

+98 11 4422 1560

**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**

Sari

**Province**

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**Postal code**

4815733971

**Phone**

+98 11 3335 0602

**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

**Street address**

Nasibeh School of Nursing and Midwifery., Vesal., west Amir mazandarani,

**City**

Sari

**Province**

Mazandaran

**Postal code**

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**Phone**

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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**Email**

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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

**Street address**

Haraz

**City**

Amol

**Province**

Mazandaran

**Postal code**

4615747845

**Phone**