Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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 khomaini amol

Full name of responsible person

khadijeh omranifar

Street address

Haraz

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Phone

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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

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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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