

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Evaluation of safety and efficacy of Desferal + Zinc nasal spray to improve clinical and pulmonary symptoms in patients with COVID-19

Protocol summary

Study aim

Reduction of viral load and inflammatory cytokines in patients with covid19

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2.3 on 60 patients. www.sealedenvelope.com was used for randomization.

Settings and conduct

in this study, 60 patients with coronavirus hospitalized in Ali Asghar Hospital in Shiraz who are eligible for inclusion in the study are randomly assigned to one of the three groups of Desferal + Zinc, Zinc and placebo. Dosing: 2 puffs every eight hours for a week In this study, the patients, the physician evaluating the patients, and the person analyzing the statistical inform, are blind.

Participants/Inclusion and exclusion criteria

Major inclusion criteria before randomization: Informed and written consent of patient with Coronavirus, Confirmation disease by clinical and laboratory signs, Patients admitted to the ward with moderate symptoms , 18 to 65 years Major exclusion criteria to study before randomization: Pregnancy and Breastfeeding, concomitant use of vitamin C, Intubated patient, History of Desferal or Zinc allergy

Intervention groups

1-Nasal spray Desferal + Zinc, chemical ingredients: desferrioxamine (500mg) plus Zinc acetate (200 mg) in a volume of 10 cc. 2-Nasal spray Zinc, chemical ingredients: Zinc acetate (200 mg) in a volume of 10 cc 3-control group: Nasal spray containing 10 cc of distilled water. Dosing: 2 Puffs in the nose every eight hours for a week

Main outcome variables

Interleukin 6, Body temperature, Cough, Oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051348N1**
Registration date: **2021-10-31, 1400/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-31, 1400/08/09**

Update count: **0**

Registration date

2021-10-31, 1400/08/09

Registrant information

Name

Navid Esmaeilzadehshahri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2631 4813

Email address

esmaeilzadeh_n@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and efficacy of Desferal + Zinc nasal spray to improve clinical and pulmonary symptoms in patients with COVID-19

Public title

Evaluation of safety and efficacy of Desferal + Zinc nasal spray

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed and written consent of patient with Coronavirus Confirmation disease by clinical and laboratory signs
Serum creatinine less than two Milligram per Deciliter
Absence of heart problems(myocarditis- heart failure)
Hemoglobin above 8 Gram per Deciliter Patients admitted to the ward with moderate symptoms 18 to 65 years

Exclusion criteria:

Ferritin lower than 100 milligram per deciliter Diabetes
History of blood coagulation problems Pregnancy and Breastfeeding
History of neurologic problems History of vision and hearing problems concomitant use of vitamin C
Intubated patient History of Desferal or Zinc allergy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method will be performed (each block includes 6 patients). Dedicated sequences and hidden codes using www.sealedenvelope.com are produced. The closed envelope method will be used to hide the allocation sequence

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients participating in the study as well as the clinician evaluating the patient and the person analyzing the data were kept blind and the researcher was aware of the drug and placebo recipients. To perform blinding during randomization using the site www.sealedenvelope.com, by activating the generate unique randomization code option, each patient will be given a special code that will be written on the medicine containers and all the containers will be exactly the same. And these codes remain confidential with the researcher until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Karimkhanzand Ave.

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2021-09-12, 1400/06/21

Ethics committee reference number

IR.SUMS.REC.1400.497

Health conditions studied

1

Description of health condition studied

covid19

ICD-10 code

U07.1

ICD-10 code description

COVID19, virus identified

Primary outcomes

1

Description

Interleukin6

Timepoint

Before and after the intervention

Method of measurement

ELISA KIT

2

Description

Body temperature

Timepoint

Before the intervention and every day during the study

Method of measurement

Thermometer

3

Description

Oxygen saturation

Timepoint

Before the intervention and every day during the study

Method of measurement

Pulse oximeter

4

Description

Cough

Timepoint

Before the intervention and every day during the study

Method of measurement

questionnaire

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

Admission period until hospital discharge

Method of measurement

Patient file

2

Description

Incidence of serious adverse events

Timepoint

Before intervention and daily during the study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1: Nasal spray Desferal + Zinc, chemical ingredients: desferrioxamine (500mg) plus Zinc acetate (200 mg) in a volume of 10 cc. Dosing: 2 Puffs in the nose every eight hours for a week

Category

Treatment - Drugs

2

Description

Intervention group 2: Nasal spray Zinc, chemical ingredients: Zinc acetate (200 mg) in a volume of 10 cc Dosing: 2 Puffs in the nose every eight hours for a week

Category

Treatment - Drugs

3

Description

Control group: Distilled water spray in a volume of 10 cc Dosing: 2 Puffs in the nose every eight hours for a week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Hospital

Full name of responsible person

Dr.Farhad Chobdar

Street address

Meshkinfam Ave

City

Shiraz

Province

Fars

Postal code

71439-18796

Phone

+98 71 3228 8907

Email

aliasghar@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.mehrzad Lotfi

Street address

Karimkhanzand Ave

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Navid Esmailzadeh Shahri
Position
Resident of Clinical Pharmacy
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Ferdowsi Ave.
City
Shiraz
Province
Fars
Postal code
۷۱۳۵۷۶۵۷۴۸
Phone
+98 71 3231 5156
Email
esmaeilzadeh_n@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
laleh mahmoudi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Akbarabad Ave.
City
Shiraz
Province
Fars
Postal code
۷۱۴۶۸۶۴۶۸۵
Phone
+98 71 3242 4127
Email
mahmoudi_l@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra EbrahimiBidgoli
Position
Student of pharmacy

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Abiverdi3 Ave.

City

Shiraz

Province

Fars

Postal code

7194763309

Phone

+98 71 3626 8360

Email

zhraabrahmy27@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information on the main outcomes studied can be shared.

When the data will become available and for how long

The data will be available after the publication of all the obtained results.

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The study or proposal protocol must be approved by the Ethics Committee of the institution or university. The rights of authors and their sponsors must be protected.

From where data/document is obtainable

Shiraz School of Pharmacy to the email address pharmacyfaculty@sums.ac.ir and contact number 00987132424128 Dr. Laleh Mahmoudi to the email address mahmoudi_l@sums.ac.ir and the contact number 00989126135992

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

Requests should be addressed to the Technology and Research Vice-chancellery of Shiraz University of Medical Sciences and the project executor should be informed. After submitting the application, a maximum of one week will be answered.

Comments