Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 21 2631 4813

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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 uniqe ramdimization 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 group2: 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
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Postal code
۱۴۳۳۶ - 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 Esmaeilzadeh Shahri

Position
Resident of Clinical Pharmacy

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
Ferdowsi Ave.

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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

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Akbarabad Ave.

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Zahra EbrahimiBidgoli

Position
Student of pharmacy

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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zhraabrahymy27@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 informed.After submitting the application, a maximum of one week will be answered .

Comments