Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Determination of dandelion herbal capsule (Dandelherb) efficacy on symptom of patient with Covid-19 virus: a clinical trial study

Protocol summary

Study aim

1. Determining and comparing the mean of CRP, ESR, WBC, RBC, Albumin, Hb, ALT, AST, Arterial oxygen saturation and Lung CT scan result in the intervention and control groups in patients with Covid-19.

Design

clinical trial with control group with parallel groups, triple blind, on 80 patients, randomised with block randomization.

Settings and conduct

80 hospitalized and eligible patients in shaheed Beheshti Hospital in Qom which their PCR test is positive) based on their file number and randomized included in to this clinical trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients Hospitalized in shaheed Beheshti Hospital in Qom with Covid-19 (their PCR test is positive). Patients between 18-65 years. Satisfaction of people to test this drug and its possible side effects.Exclusion criteria: History of allergy to plants of asteraceae. bile duct and intestinal obstruction. GI diseases,Diabetes and kidney failure. Alcohol consumption history Pregnant and lactating women and Married women who are in childbearing age and do not use reliable contraception method. Weight below 50 kg.Consumers of Lithium, digoxin, corticosteroids, niacin / nicotinic acid, metronidazole, disulfiram, tetracycline and fluoroquinolone antibiotics, hypoglycemic drugs, antiplatelet drugs, diuretics, Antacids. Consumers of s bloodroot, cat’s claw, chamomile, chaparral, chasteberry, damiana, Echinacea angustifolia, goldenseal, grapefruit juice, licorice, oregano, redclover,St.John’swort, wildcherry, andyucca.

Intervention groups

Intervention group: Dandelion capsule, 300 mg 3 times a day (900 mg), for 40 days. Control group: placebo capsule, 300 mg 3 times a day (900 mg), for 40 days.

Main outcome variables

CRP؛ ESR؛ WBC؛ RBC؛ Albumin؛ Hb؛ ALT؛ AST؛ Arterial oxygen saturation؛ Lung CT scan

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180513039641N2**
Registration date: **2020-07-27, 1399/05/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-27, 1399/05/06**
Update count: **0**

Registration date

2020-07-27, 1399/05/06

Registrant information

Name

Hoda Abolhasani

Name of organization / entity

Country

Iran (Islamic Republic of)

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habolhasani@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-26, 1399/05/05

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Determination of dandelion herbal capsule (Dandelherb) efficacy on symptom of patient with Covid-19 virus: a clinical trial study

Public title
Determination of dandelion capsule on patient with Covid-19 virus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients Hospitalized in shaheed Beheshti Hospital in Qom with Covid-19 (their PCR test is positive). Patients between 18-65 years. Satisfaction of people to test this drug and its possible side effects.

Exclusion criteria:
History of allergy to plants of asteraceae. bile duct and intestinal obstruction. acute cholecystitis, empyema, acute gall bladder inflammation. Gastrointestinal diseases, gastritis, irritable bowel syndrome. Diabetes and kidney failure. Alcohol consumption history (more than 10 grams per day for women and more than 20 grams per day for men). Pregnant and lactating women and Married women who are in childbearing age and do not use reliable contraception method. Weight below 50 kg Uncontrolled underlying diseases such as high blood pressure and .... Consumers of Lithium, digoxin, corticosteroids such as prednisone, niacin / nicotinic acid, metronidazole, disulfiram, tetracycline and fluoroquinolone antibiotics (such as ciprofloxacin), hypoglycemic drugs, antiplatelet drugs, diuretics, Antacids such as famotidine and s omeprazole. Consumers of s bloodroot, cat’s claw, chamomile, chaparral, chasteberry, damiana, Echinacea angustifolia, goldenseal, grapefruit juice, licorice, oregano, redclover,St.John’swort, wildcherry, andyucca.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be assigned to two groups of intervention and control by block randomization. For this purpose blocks of size 4 will be used. Six blocks will include BAAB, ABBA, BABA, BBAA, ABAB, AABB. A number from 1 to 6 is given to each of the mentioned blocks and then a random sequence of twenty is generated from 1 to 6 with Exell program and generate random numbers option. Afterward according to the relevant block, the treatment is assigned to the groups randomly. To hide the random allocation, the numbered dark envelopes will be used, in which the group name is specified in the random sequence generated. Then, according to the order of entering samples, for the first patient the envelope number one is opened and the group will be identified until the end.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be performed in a double-blind manner. Unlabeled drugs in similar packages with a unique code will be prepared and a third person which don't contributed directly in the study, will be given the drugs to patients.In this case, patients will not inform the type of treatment they received. Also, the patient examining physician does not inform the type of received intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qom University of Medical Sciences

Street address
No. 83, 4th alley, 1.1 alley, Safashahr Blvd

City
Qom

Province
Ghoum

Postal code
3716987366

Approval date
2020-07-21, 1399/04/31

Ethics committee reference number
IR.MUQ.REC.1399.148

Health conditions studied

1

Description of health condition studied
Covid-19 infectious disease

ICD-10 code
U07.1

ICD-10 code description
Coronavirus infection :COVID-19, virus identified (a disease diagnosis of COVID-19 confirmed by laboratory

testing)

Primary outcomes

1

Description
C-Reactive Protein
Timepoint
Measurement of C-Reactive Protein at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood test

2

Description
white blood cell
Timepoint
Measurement of white blood cell at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood test

3

Description
Red blood cell
Timepoint
Measurement of Red blood cell at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood Test

4

Description
Hemoglobin
Timepoint
Measurement of hemoglobin at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood test

5

Description
Albumin
Timepoint
Measurement of Albumin at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood Test

6

Description
Alanine aminotransferase
Timepoint
Measurement of Alanine aminotransferase at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood Test

7

Description
Aspartate transaminase
Timepoint
Measurement of Aspartate transaminase at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood Test

8

Description
Creatinine
Timepoint
Measurement of Creatinine at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood Test

9

Description
Blood Urea Nitrogen
Timepoint
Measurement of Blood Urea Nitrogen at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood Test

10

Description
Total Bilirubin
Timepoint
Measurement of Total Bilirubin at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood Test

11

Description
Direct Bilirubin
Timepoint
Measurement of Direct Bilirubin at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood Test

12

Description
Alkaline Phosphatase
Timepoint
Measurement of Alkaline Phosphatase at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Blood Test

13

Description
Blood oxygen saturation
Timepoint
Measurement of Blood oxygen saturation at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
Pulse Oximeter

14

Description
CT scan of the lungs
Timepoint
Measurement of CT scan of the lungs at the beginning of the study (before the start of the study) and 40 days after the start of dandelion capsule
Method of measurement
CT scan

Secondary outcomes

1

Description
high sensitivity C-Reactive Protein
Timepoint
Before and after medication with Dandelion cap
Method of measurement
Blood Test

Intervention groups

1

Description
Intervention group: Oral yellow herbal Dandelion Capsule 300 mg with production license by the Managing Director of Nik Daroie Shafasaz Amiran Company and produced in Booali Daro Pharmaceutical Factory of Qom, 900 mg (3 capsules) per day after meals and for 40 days will be consumed by the candidates. It should be noted that hospitalized patients with positive COVID-19 test, also receive standard COVID-19 treatments, including interferon beta-1b, dexamethasone, and remdesivir.
Category
Treatment - Drugs

2

Description
Control group: Oral herbal Placebo Dandelion Capsule 300 mg contain starch and similar to dandelion cap (yellow) produced in Booali Daro Pharmaceutical Factory of Qom, 900 mg (3 capsules) per day after meals and for 40 days will be consumed by the candidates. It should be noted that hospitalized patients with positive COVID-19 test, also receive standard COVID-19 treatments, including interferon beta-1b, dexamethasone, and remdesivir.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shaheed Beheshti Medical Education Center
Full name of responsible person
Hoda Abolhasani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Ehsan Sharifipour
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No. 83, Alley 4, Alley 1/1, Safashahr St.
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Reihaneh Tabaraie

Position

Assistance professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistance professor

Latest degree

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Other areas of specialty/work

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Latest degree

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After receiving the results of the study, there are plans to publish the article in valid journals

When the data will become available and for how long

all the time

To whom data/document is available

Depending on the journal in which the study is published

Under which criteria data/document could be used

After receiving the results of the study, there are plans to publish the article in valid journals

From where data/document is obtainable

Depending on the journal in which the study is published

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

Depending on the journal in which the study is published

Comments

Depending on the journal in which the study is published