Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of propolis supplementation on anthropometric parameters, oxidative stress and inflammatory status, and mortality rate in patients with severe pneumonia

Protocol summary

Study aim

evaluating the effects of propolis administration on anthropometric parameters, oxidative stress and inflammatory status, and mortality rate in patients with severe pneumonia

Design

A clinical trial with a control group, with a parallel intervention group, double-blind, randomized, phase 3 on 42 patients, a random sequence generation software is used for randomization.

Settings and conduct

the research will be conducted at Imam Khomeini Hospital in Urmia. People in the intervention group will receive tablets containing propolis supplement prepared by Soren Tek Company (containing100 mg of propolis extract twice a day) and people in the control group will also receive the same amount of placebo tablets. tablets containing propolis supplement and placebo will be completely similar in appearance. Only the person responsible for packing tablets containing propolis and placebo will know about the relevant codes

Participants/Inclusion and exclusion criteria

inclusion criteria: clinical symptoms of pneumonia like coughs that have recently started or have gotten worse, purulent sputum, witnessing pneumonia symptoms in the chest scan, dyspnea or tachypnea, mechanical ventilation, two or more of the SIRS symptoms exclusion criteria: asthma or allergies, acute heart failure phase, cystic fibrosis, malignancies, allergy to propolis, pregnancy or lactation

Intervention groups

patients in the intervention group will receive tablets containing propolis supplement prepared by Soren Tek Company (containing 100 mg of propolis extract twice a day) and patients in the control group will also receive the same amount of placebo tablets.

Main outcome variables

Changes in oxidative stress parameters including MDA and TAC, inflammatory parameters including ESR and CRP, as well as qSOFA scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220902055856N1**
Registration date: **2022-09-17, 1401/06/26**
Registration timing: **prospective**

Last update: **2022-09-17, 1401/06/26**
Update count: **0**

Registration date

2022-09-17, 1401/06/26

Registrant information

Name

Parsa Sameei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2025-09-23, 1404/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of propolis supplementation on anthropometric parameters, oxidative stress and inflammatory status, and mortality rate in patients with severe pneumonia

Public title
effects of propolis in pneumonia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
the patient must be at least 18 years old and should be diagnosed with pneumonia which requires medicinal intervention pneumonia symptoms including: cough which has just started or gotten worst, purulent sputum, witnessing pneumonia-related symptoms in the chest examination, dyspnea (a breathing rate more than 20 per minute) or tachycardia, or mechanical ventilation should be seen in the first 72 hours 2 or more of the SIRS symptoms in the last 24 hours including: a body temperature below 36 or above 38, heartbeat above 90 per minute, Breathing rate above 20 per minute, or a CO2 blood concentration above 4.2 KPa, WBC>12000/mm3, OR<4000.mm3, OR>10%
Exclusion criteria:
ashtma allergies known rheumatological diseases acute heart failure malignancies cystic fibrosis and chronic kidney failure with a GFR below 30 ml/min hepatic failure with a C child score a history of allergy to propolis usage of any other antioxidants patients with a transplanted organ patients receiving immunosuppressive drugs pregnancy or lactation
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**
More than 1 sample in each individual
Number of samples in each individual: **2**
2 Blood samples will be acquired from each of the patients
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of people in each of the study groups (supplement and placebo) will be done by "Random Allocation" software and using the block random division method (blocks of 4). Allocation concealment will be used to reduce the selection bias error. After admittion of the patient to the ward and obtaining the necessary criteria to enter the study, they are randomly assigned to sealed envelopes with unique codes generated by Random Allocation Software. The codes along with groups A and B (supplement group and placebo indicators) were generated at the beginning of the study by one of the collaborators of the project, who is not involved in any of the clinical phases of the intervention and sampling, and will remain with him until the end of the study. The presenters will remain unaware of the concept of codes and groups until the end of the study. Codes A and B are inserted on the envelopes in order to specify two separate groups. After allocating each group A envelope or B to the patient enrolled in the study, the envelope is opened and the code inside the envelope, which contains 4 numbers (for example 5372), which has no meaning and does not indicate any concept and is completely random, will be inserted on the supplement box. Patients are divided only according to the A or B code and the numbers inside the floor criteria envelope There is no classification and these codes are only used for labeling on medicine and placebo cans.
Blinding (investigator's opinion)
Double blinded
Blinding description
both patients and researchers do not know about the type of drug that receive (Propolis or placebo)and are blinded. placebo are prepared in the same shape, size, and color of propolis capsules. the medicine and the placebo are coded in the form of computerized randomization numbers. then they are given to the researcher and the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urjans street, Resalat blvd, Oromiye
City
Oroumieh
Province
West Azarbaijan
Postal code
5714783734
Approval date
2022-08-24, 1401/06/02

Ethics committee reference number
IR.UMSU.REC.1401.217

Health conditions studied

1

Description of health condition studied
Severe pneumonia
ICD-10 code
A40.3
ICD-10 code description
Sepsis due to Streptococcus pneumoniae

Primary outcomes

1

Description
measuring the ESR parameter (erythrocyte sedimentation rate)
Timepoint
At the beginning of the study and also 7 days after the start of the intervention
Method of measurement
ESR: will be measured by observing

2

Description
CRP (C reactive protein) levels
Timepoint
At the beginning of the study and also 7 days after the start of the intervention
Method of measurement
CRP: will be measured with special kits

Secondary outcomes

1

Description
measuring MDA levels (malondialdehyde)
Timepoint
At the beginning of the study and also 7 days after the start of the intervention
Method of measurement
by MDA kits purchased from Padgine Teb Co

2

Description
measuring TAC levels (Total antioxidant capacity)
Timepoint
At the beginning of the study and also 7 days after the start of the intervention
Method of measurement
by TCA kits purchased from Padgine Teb Co

3

Description
WBC changes (White blood cells)
Timepoint
At the beginning of the study and also 7 days after the start of the intervention
Method of measurement
by cell counter device

4

Description
Reducing the length of hospitalization
Timepoint
From admission to discharge
Method of measurement
Based on the date of admission and discharge recorded in the patient's file

Intervention groups

1

Description
Intervention group: This group will receive 100 mg propolis tablets bought from suren tek company twice a day for 7 days. The patient's condition and consumption of supplements will be followed up by the researcher on a daily basis. All patients will receive standard treatment for severe pneumonia, which includes parenteral antibiotics and, in certain cases, corticosteroids. If the patient does not tolerate the supplement or if an intolerable complication occurs, the patient will be excluded from the study.
Category
Treatment - Drugs

2

Description
Control group: this group will receive a placebo tablet with the same appearance characteristics as the original tablets. The duration of the placebo appointment will be 7 days, just like the main intervention of the study.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Parsa Sameei
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Ershad street, Ayatollah modarres blvd, Oroumiyeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Parsa Sameei
Position
student
Latest degree
A Level or less
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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