

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effect of capsules containing natural products on serum level of biomarkers related to air pollution

Protocol summary

Study aim

Comparison of the effect of 250 mg and 500 mg air pollution capsules on changes in serum levels of glutathione peroxidase, total antioxidant, CRP, fibrinogen, WBC, hematocrit and blood pressure in the control and treatment groups

Design

Clinical trial with control group, parallel groups, double blind and randomized, phase 3. Sample size will be equal to 90

Settings and conduct

The study will be carried out on military staffs in Tehran who are exposed to air pollution. Subjects will be randomly divided into three groups (500, and 250 mg air capsules and placebo) The capsules are given in two phases, each phase for 3 weeks, The study design is a way that executive agents, samples, and statistics experts do not know the contents of the capsules in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria include occupational activity of at least one year in central Tehran, ages 21 to 60 years and no significant internal disease. Exclusion criteria included developing a drug allergic reaction during the study and not taking the intervention (less than 5 weeks after beginning the study).

Intervention groups

The subjects will be assigned into three groups: group 1 (intervention) 500 mg air pollution capsule, group 2 (intervention) 250 mg air pollution capsule and group 3 (Control) placebo capsules.

Main outcome variables

The effect of an Iranian medicine product on the health complications of air pollution

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180611040053N2**

Registration date: **2020-02-23, 1398/12/04**

Registration timing: **prospective**

Last update: **2020-02-23, 1398/12/04**

Update count: **0**

Registration date

2020-02-23, 1398/12/04

Registrant information

Name

Mohammad Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8755 4484

Email address

mghmed@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of capsules containing natural products on serum level of biomarkers related to air pollution

Public title

Evaluation of the effect of a functional capsule on the complications of air pollution

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Signing informed consent working for more than 1 year in central regions in Tehran age between 21-60 years No significant renal or hepatic or pulmonary disease No hyperthyroidism No smoking or addiction to any drugs No cardiovascular diseases No consuming antioxidant medications or supplements No current fissures and hemorrhoids

Exclusion criteria:

history of sensitivity to herbal medications

Age

From **21 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects in the study will be randomly divided into three groups. In this case first 5 triad blocks (letters A, B and C) will be made up for each six possible conditions (totally 30 blocks). These blocks will then be randomly selected and grouped together. So individuals will be allocated to the groups according each selected letter.

Blinding (investigator's opinion)

Single blinded

Blinding description

Individuals in all three groups will receive capsules of the same shape, size, and packaging. But on each package according to the type of capsules will be written; Model 1, Model 2 and Model 3 and the content of each model will be kept with the project supervisor so the presenters, study subjects and statistics expert will not be aware of the contents of the capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Molla Sadra street, Sheikh Bahae street, Shahid Nosrati avenue

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.BMSU.REC.1397.347

Health conditions studied

1

Description of health condition studied

medical effects of air pollution

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum levels of glutathione peroxidase, total antioxidant, CRP, fibrinogen, WBC and hematocrit

Timepoint

Two times, before the intervention and six weeks after beginning the intervention

Method of measurement

medical laboratory

Secondary outcomes

1

Description

Blood pressure

Timepoint

Two times, before the intervention and six weeks after beginning the intervention

Method of measurement

Mercury sphygmomanometer

Intervention groups

1

Description

First intervention group: Administration of Webair 500 milligram capsule containing processed saffron powder,

patience yellow and cream produced by Barij Essence Company Two capsules will be consumed three times a week half hours before meal for 6 weeks.

Category

Prevention

2

Description

Second intervention group: Administration of Webair 250 milligram capsule containing processed saffron powder, patience yellow and cream produced by Barij Essence Company Two capsules will be consumed three times a week half hours before meal for 6 weeks.

Category

Prevention

3

Description

Control group: Administration of placebo capsule produced by Barij Essence Company Two capsules are consumed three times a week half hours before a meal for 6 weeks

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah University of Medical Sciences

Full name of responsible person

Gholamhossein Pourtaghi

Street address

Baqiyatallah University of Medical Sciences, Shahid Nosrati ave, Sheikh Bahaaee street, Molla Sadra street,

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mgamed@bmsu.ac.ir

Web page address

https://www.ircct.ir/user/trial/41826/update/recruitment_center

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Barij Essense Company

Full name of responsible person

Leila Mohammad Taghizadeh

Street address

Kashan- Delijan road (kilometer 44)

City

Kashan

Province

Isfahan

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3795191916

Phone

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Email

ghpourtaghi@yahoo.com

Web page address

<http://barijessence.com/>

Grant name

Research credit

Grant code / Reference number

97000263

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

Yes

Title of funding source

Barij Essense Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Barij Essense

Full name of responsible person

Leila Mohammad Taghizadeh

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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http://barijessence.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohammad Ghasemi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Occupational Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Gholam Hossein Pourtaghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Health

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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