

Effect of black seed on immunity in young healthy Saudi volunteers

Submission date 29/10/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/11/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/12/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Nigella sativa (NS) is a widely used medicinal plant throughout the world and is thought to have numerous health benefits including antioxidant, antimicrobial, anticancer and immune system effects. This study is designed to assess the effects of NS on the immune systems of healthy university students.

Who can participate?

Healthy university students

What does the study involve?

Participants are randomly assigned to take NS supplements (0.5, 1.0 or 2.0 g) or charcoal pills for 4 weeks. At the start and end of the study, participants have several routine clinical tests.

What are the possible benefits and risks of participating?

NS is expected to enhance the immune system in the participants with no side effects.

Where is the study run from?

Imam Abdulrahman bin Faisal University (Saudi Arabia)

When is the study starting and how long is it expected to run for?

January 2020 to December 2020

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Prof. Abdullah Bamosa

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

032

Study information

Scientific Title

Effect of nigella sativa on immunity in young healthy Saudi volunteers

Study objectives

Nigella sativa will enhance immunity in humans

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/01/2020 Institutional review board of Imam Abdulrahman bin Faisal University (Dammam, 31451, Saudi Arabia; +966 (0)558808829; dsr@iau.edu.sa), ref: rRB -2020-UGS-01-032

Study design

Single-centre randomized double-blind placebo-controlled clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Immunity of healthy individuals

Interventions

The study will be conducted on healthy male students studying in IAU and blood sampling will be carried out in the main campus university clinic. Students will take the intervention for 1 month and will be divided into four groups; three will take different doses of black seed and the fourth will serve as a control. A total of 120 participants will be enrolled in the study, 30 participants will be randomly allocated to each group. Randomization will be achieved through a computerized table generated by the appropriate program. The first group is the control group – placebo - and they will be given 162 mg of an activated charcoal oral capsule, the second group will receive one capsule of 500 mg NS, the third group will receive two capsules of NS, and the fourth group will take four capsules.

Intervention Type

Supplement

Primary outcome measure

Measured at baseline and 4 weeks:

1. Cytokines (IL-1, IL-4, IL-6, IL-10 and TNF) measured using ELISA
2. Immunoglobulins (IgG, IgM) measured using ELISA
3. Cellular immunity (CD4 & CD8) measured using flow cytometry

Secondary outcome measures

Measured at baseline and 4 weeks:

1. Blood pressure measured using sphygmomanometer
2. Heart rate measured by the researcher
3. Liver function test measured using Alinity ci & hq machines (Abbot, USA)
4. Complete blood count measured using Alinity ci & hq machines (Abbot, USA)
5. Renal function test measured using Alinity ci & hq machines (Abbot, USA)
6. General health measured using a questionnaire

Overall study start date

29/01/2020

Completion date

30/12/2020

Eligibility

Key inclusion criteria

1. Healthy male IAU students
2. Age between 18 - 25 years
3. BMI 18.5 - 29.9 kg/m²

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

25 Years

Sex

Male

Target number of participants

120

Total final enrolment

64

Key exclusion criteria

1. Students with any acute or chronic illness (unless acute illness occurred during the study)
2. Students with abnormalities in the basic laboratory investigations
3. Participants with less than 90% compliance

Date of first enrolment

01/02/2020

Date of final enrolment

01/04/2020

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

Imam Abdurahman bin Faisal University

Primary health care center

Dammam

Saudi Arabia
31451

Sponsor information

Organisation

Imam Abdularahman bin Faisal University

Sponsor details

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Sponsor type

Government

Website

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Funder(s)

Funder type

University/education

Funder Name

Imam Abdularahman bin Faisal University

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/01/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. All data including basic participant information, primary and secondary outcomes and analysed data will be available for 2 years after the study

endpoint. data may be sent by email upon request from authorised body with no personal participant information.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			02/12/2020	No	No
Results article		25/11/2021	14/03/2022	Yes	No
Results article		18/10/2023	21/12/2023	Yes	No