ISRCTN14150499 https://doi.org/10.1186/ISRCTN14150499

Effect of black seed on immunity in young healthy Saudi volunteers

Submission date	Recruitment status	[_] Prospectively registered
29/10/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/11/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/12/2023	Other	

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
25 years

Sex
Male

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 Abdularahman bin Faisal University
Primary health care center
Dammam
Saudi Arabia
31451

Sponsor information

Organisation
Imam Abdularahman bin Faisal University

Funder(s)

Funder type
University/education

Funder Name
Imam Abdulrahman bin Faisal University

Results and Publications

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?
Results article		25/11/2021	14/03/2022	Yes	No
Results article		18/10/2023	21/12/2023	Yes	No
Protocol file			02/12/2020	No	No