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Effects of Black Seed supplementation on management outcome of partially controlled asthma

Submission date	Recruitment status	[_] Prospectively registered
26/08/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/11/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/02/2017	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
KFU-LEC-130. date 11/7/2009

Study information

Scientific Title
Effects of Nigella sativa supplementation on airway resistance and inflammatory mediators in patients with partly controlled asthma

Study objectives
Treatment supplementation with whole black seeds (Nigella sativa) in asthmatic patients has benificial effects on signs and symptoms, lung function tests and inflammatory markers in the serum, sputum and breath.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Committee of Biomedical Ethics at King Faisal University, 11/07/2009, ref: KFU-LEC-130

Study design
Interventional single-centre double-blind randomised placebo-controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma (partly controlled)

Interventions
1. Group 1 (n = 30) will be given a placebo and serve as the control group
2. Group 2 (n = 30) will be given 500 mg of Nigella sativa
3. Group 3 (n = 30) will be given 1 g Nigella sativa
4. Group 4 (n = 30) will be given 2 g Nigella sativa

Nigella sativa will be given in the form of 500 mg powder capsules (Bio Extracts, Sri Lanka). A single capsule in the morning for group 2 and in divided doses (morning and evening) for groups 3 and 4. The control group will be given capsules similar to those given to the test group but filled with a placebo.

The patients will be assigned to the control and test groups' randomly, by using table of random numbers. The ongoing conventional treatment of the patients will not be interrupted or modified. The study subjects will be evaluated four times during the course of the study; at the time of recruitment (baseline) and monthly thereafter for 3 months.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nigella sativa supplementation

Primary outcome(s)

The following assessments will be made during all the four visits to determine the effect of treatment with Nigella:
1. Anthropometric measurements including weight (measured using a digital Holtain electronic scale [150 ± 0.1 kg]) and height (measured with a Holtain stadiometer to the nearest millimetre). These measurements will be used for interpretation of lung function tests.
2. Clinical assessment, performed by pulmonologists in the research team at King Fahad Hospital of the University in Al-Khobar. It will be carried out according to the criteria adopted by the Global Initiative for Asthma (GINA 2008) to determine level of control of the patients. The asthma control test questionnaire will be filled for every patient. The type of medication used will also be recorded and any modifications needed will be noted and recorded.
3. Lung function tests: Peak expiratory flow (PEF), Forced Expiratory Volume in First second (FEV1) and forced vital capacity (FVC) will be measured during each visit for the sake of evaluating control. FEV1 and FVC will be measured using Vitalograph Pneumotrac® model 6800. Wright peak flow meter will be used for measurement of PEF. In addition, another independent indicator of asthma control; variability in airflow limitation will be evaluated. For this sake a hand held portable Peak Expiratory Flow meter will be given to every patient in the study. The patients will be asked to measure their PEF twice every day. This will be preceded by careful explanation of the procedure to the patients. These measurements will be performed during the week preceding the start of the trial to establish baseline data and will be repeated during the week preceding every visit. The patients will be reminded in due time. PEF is measured first thing in the morning before treatment is taken, when values are often close to their lowest and last thing at night. PEF variability will be evaluated by obtaining the difference between the maximum and minimum over the week and dividing this by the mean value over that week. FEV1, forced expiratory volume during the mid-part of vital capacity (FEF25-75%) and FVC will be measured on the day of each of the four visits.
4. Exhaled Nitric Oxide (FeNO) levels will be measured at all the visits by using Niox Mino® (Aerocrine AB, Sweden). The results will be managed by software Niox Mino Data Manager®.
5. Immune cells and inflammatory mediators: Total and differential count of the white blood cells will be done for all patients in all the four visits including the recruitment visit. Th1 and Th2 counts will also be performed. In addition eosinophil count will be done in a sample of induced sputum. Interleukins 4, 5, 8, 10, 13 and Tumour Necrosis Factor (TNF) will be measured in blood and sputum. Leukotrienes, LTB4, LTC4, LTD4 and LTE4 will also be measured in blood as well as in the induced sputum. T helper-1 (Th1) and T helper-2 (Th2) will be evaluated by flow cytometry. The leukotrienes and interleukins and other cytokines will be done by Enzyme Linked Immunosorbent Assay (ELISA) with Quantikines kits purchased from RD systems using the original method described by Yalo and Berson. Sputum induction will be performed using a method previously described. In brief, the procedure will be started 10 minutes after the administration of 400 µg of inhaled salbutamol. Hypertonic saline (3%) will be inhaled using a nebuliser for 15 minute or until enough sputum is obtained for analysis. The procedure will be terminated if there is a decrease in FEV1 20% in relation to the baseline value occurs. Saline nebulisation will be performed using a Fisoneb ultrasonic nebulizer (Fisons, Pickering, Ontario, Canada), with an output rate of 0.87 mL/min and particles presenting a median aerodynamic mass diameter of 5.58 µm. During the inhalation period, FEV1 will be measured every three minutes to ensure the safety of the test. Sputum samples will be processed and analysed within two hours. An induced sputum sample appropriate for analysis will be defined as that containing expectorated material with cellular viability greater than 50% and contamination by oropharyngeal squamous cells lower than 20%, as well as being of a quantity sufficient for differential counts of 400 cells. The standard protocol presented by Lacy and colleagues will be used (Lacy et al 2005). In the induced sputum specimen collected the following will be measured:
5.1. Total and differential white cell count
5.2. IgE
5.3. Interleukins 4, 5, 8, 10, 13 and TNF-alpha

5.4. Leukotriens LTB4, LTC4, LTD4 and LTE4
5.5. Eosinophil cationic protein
5.6. Eotaxin

All related information and results for each patient will be recorded in a separate proforma for regular follow up and quick reference.

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Established diagnosis of partly controlled asthma
2. Aged 18 - 60 years old, either sex
3. Willingness to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Patients whose compliance is less than 90%
2. Patients having chronic diseases (heart, liver or kidney disease, diabetes)
3. Patients on long-term oral steroids, leukotriene modifiers, anti-cholinergics, theophylline and cromones

Date of first enrolment
01/10/2009

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Faisal University
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Sponsor information

Organisation
King Faisal University (Saudi Arabia)

ROR
https://ror.org/00dn43547

Funder(s)

Funder type
University/education

Funder Name
King Faisal University (Saudi Arabia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017		Yes	No