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Efficacy of ascorbic acid and N-Acetylcysteine (NAC) supplementation on nutritional, antioxidant status, and respiratory function of male Chronic Obstructive Pulmonary Disease (COPD) patients

Submission date 05/12/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/01/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/08/2014	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease. It is characterized by a narrowing of the airways in the lungs. There is evidence that an imbalance between oxidants and antioxidants or oxidative stress that may play a role in many of the processes involved in the progress and severity of COPD. These include increased secretion of mucus and increased inflammation in the lungs in response to breathing tobacco smoke. COPD has multiple consequences for the whole body, such as weight loss. It is now thought that oxidative stress may extend beyond the lungs and is involved in these effects. Antioxidant therapy therefore would seem to be a logical treatment approach in COPD. There is a need for more potent antioxidant treatments to test whether antioxidant drugs could be used as a new strategy for the prevention and treatment of COPD. We hope that by doing this study, we will be able to improve nutritional, antioxidant status, and respiratory function in patients suffering from COPD.

Who can participate?

Patients aged between 35 to 75 years old with COPD.

What does the study involve?

Participants will be randomly allocated to one of four groups for 6 months to take one pill daily. Group A will receive vitamin C, group B will receive N-Acetylcysteine (NAC), and the group C will receive both vitamin C and NAC. The control group will not receive any supplements. Weight, height, body mass index, body composition and food intake will be assessed and blood samples will be taken at the start of the study, at month 3 and at month 6. For measuring body composition and blood sampling the patient should fast for at least 8 hours before the procedure. Patients will also undergo breathing tests.

What are the possible benefits and risks of participating?
The research performed will contribute greatly to science and medicine. It will benefit us in terms of understanding further the disease concerned and may help to improve the health status of patients with COPD in the future. There are no additional risks involved and vitamin C and NAC supplementation will not cause any side effects. The dosage used for vitamin C is based on the Recommended Dietary Intake (RDI) for patients and the dosage for NAC is the safety range based on previous studies.

Where is the study run from?
The study takes place at two outpatients departments (OPD) of medical center of Universiti Kebangsaan Malaysia (PPUKM) and Institute of Respiratory Medicine (IPR) in Malaysia.

When is the study starting and how long is it expected to run for?
Patients will be enrolled in the study between June 2009 and March 2011.

Who is funding the study?
Universiti Kebangsaan Malaysia.

Who is the main contact?
Professor Dr Suzana Shahar
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UKM 1.5.3.5/244/SPP/NN-056-2009

Study information

Scientific Title
Efficacy of ascorbic acid and/ N-Acetylcysteine (NAC) supplementation on nutritional, antioxidant status, and respiratory function of male Chronic Obstructive Pulmonary Disease (COPD) patients: a randomized controlled trial

Acronym
COPD

Study objectives
1. Antioxidants (ascorbic acid, glutathione) either alone or in combination had a positive effect after 3 months supplementation on nutritional status among male COPD patients at UKM Medical Centre (PPUKM) and Institute of Respiratory Medicine (Institut Perubatan Respiratori) (IPR)
2. Antioxidants (ascorbic acid, glutathione) either alone or in combination had a positive effect after 3 months supplementation on respiratory function among male COPD patients at PPUKM and IPR
3. Antioxidants (ascorbic acid, glutathione) either alone or in combination had a positive effect after 3 months supplementation on antioxidant and oxidative stress in male patients with COPD at PPUKM and IPR

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: UKM 1.5.3.5/244/SPP/NN-056-2009

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Ms. Elham Pirabbasi, el123_2008@yahoo.com to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease

Interventions
Arm A: receive vitamin C supplement (500 mg) effervescent pills orally, once per day for 6 months
Arm B: receive NAC (600 mg) effervescent pills orally, once per day for 6 months
Arm C: receive combination of both vitamin C (500 mg) and NAC (600 mg) effervescent pills, once per day for 6 months
Arm D: control group (not taking placebo), follow-up for 6 months

All trial arms will randomly divided and matched for age, gender, smoking index, number of cigarettes (pack year), duration of COPD and family income. Anthropometry measurements, body composition, spirometry and plasma antioxidant and oxidative stress will be assessed for all trial arms before intervention and every 3 months (month 3 and month 6) of the intervention.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin C, N-Acetylcysteine

Primary outcome measure
1. Anthropometry
2. Food record
3. Body composition
4. Spirometry
5. Plasma antioxidants
6. Plasma oxidative stress biomarkers
Measured at baseline and every 3 months (month 3 and month 6) of the intervention

Secondary outcome measures
No secondary outcome measures

Overall study start date
24/07/2009

Completion date
15/03/2011

Eligibility

Key inclusion criteria
1. An established clinical history of COPD diagnosed by the physician, with pre-bronchodilator forced expiratory volume in 1 second (FEV1) % predicted 3080%, which was defined as stage I, II and III based on the American Thoracic Society (2004) definition.
2. Patients aged between 35 to 75 years old who did not take any antioxidant supplementation for the past three months, not diagnosed with co-morbidities such as diabetes mellitus (DM), tuberculosis (TB), and inflammatory disease, and had not been hospitalized for the past three months prior to the study

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
79 subjects participated

Key exclusion criteria
1. Patients with co-morbidities such as diabetes mellitus (DM), tuberculosis (TB) and inflammatory disease and taking about 500 mg vitamin C through their diet or vitamin C supplements
2. The patients who took drugs such as aspirin, estrogen, amphetamine and cholesyramine regularly for the past three months which affected absorption of vitamin C

Date of first enrolment
24/07/2009

Date of final enrolment
15/03/2011

Locations

Countries of recruitment
Malaysia

Study participating centre
Dietetic Programme
Kuala Lumpur
Malaysia
50300

Sponsor information

Organisation
National University of Malaysia (Universiti Kebangsaan Malaysia) (Malaysia)

Sponsor details
c/o Prof. Dr. Suzana Shahar
Dietetic Programme
Center for Health Care Sciences

Faculty of Health Sciences
Universiti Kebangsaan Malaysia
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50300

Sponsor type
University/education

Website
http://www.ukm.my/v3/

ROR
https://ror.org/00bw8d226

Funder(s)

Funder type
University/education

Funder Name
National University of Malaysia (Universiti Kebangsaan Malaysia) (Malaysia)

Alternative Name(s)
Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration