

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

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<b>Registration date</b> 20/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/08/2014	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**Contact name**

Ms Elham Pirabbasi

**Contact details**

Dietetic Programme

Center for Health Care Sciences

Faculty of Health Sciences

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Kuala Lumpur

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50300

## Additional identifiers

**Protocol serial number**

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

## **Study type(s)**

Treatment

## **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(s)**

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

**Key secondary outcome(s)**

No secondary outcome measures

**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  $\leq 30\%$ , 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**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 cholestyramine 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)

**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**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration