

Respirator N95 masks to prevent the inhalation of urban air pollutants

Submission date 18/06/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/08/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/07/2013	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

We are carrying out a study of 40 volunteers to see if face masks reduce the amount of air pollutants in urine. These chemicals measure how much air pollution a person has breathed over the past one or two days. According to the United Nations, Hanoi is one of the top six cities with the highest amount of pollution in the world. Air pollution is believed to cause different kinds of diseases in people, especially in developing countries. The long-term goal of this study is to see if the R95 face mask can reduce the amount of respiratory diseases (diseases that make it hard to breathe) caused by air pollution. The immediate goal of the study is to investigate whether the face mask reduces the amount of air pollution breathed by 40 healthy volunteers.

Who can participate?

This study aims to recruit 40 healthy adult volunteers (20 males and 20 females) who work outside on the street for at least 4 hours every 24 hours. Examples of people that work on the street include motorbike drivers, street vendors, gas station workers and construction workers.

What does the study involve?

The study will last two weeks. All volunteers will begin the study at the same time. There will be two different schedules describing when and for how long volunteers should wear their masks. Volunteers will be randomly assigned to one of these two schedules. Certain chemicals in urine measure how much air pollution a person has inhaled during the past one or two days. Urine samples will be collected on Tuesday and Friday afternoons, and these chemicals will be measured to determine how much air pollution the volunteer has breathed. Two study employees will visit volunteers at their workplace to check whether or not volunteers are actually wearing their face masks. Study employees will visit volunteers without telling them in advance and at random times. Study employees will remind volunteers to wear their masks by sending them text messages each day.

What are the possible benefits and risks of participating?

The study will pay participants 3 USD in Vietnamese dollars for each urine specimen and 1 USD for each day participants write in their diary. If participants follow all instructions correctly for the 15 days of the study, they will receive 30 USD in Vietnamese dollars.

Where is the study run from?

The study is run by researchers at the Oxford University Clinical Research Unit (OUCRU) Viet Nam, in association with the London School of Hygiene and Tropical Medicine (LSHTM) and the Hospital for Tropical Diseases in Ho Chi Minh City.

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

The study ran from July to October 2009 for a total of 3 months. The study has been completed.

Who is funding the study?

The Wellcome Trust (UK).

Who is the main contact?

The Clinical Trials Unit at the Oxford University Clinical Research Unit Viet Nam. +84839241983

Contact information

Type(s)

Scientific

Contact name

Dr Heiman Wertheim

Contact details

Oxford University Clinical Research Unit
National Institute of Infectious and Tropical Diseases
Bach Mai Hospital
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Hanoi
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Additional identifiers

Protocol serial number

03 09

Study information

Scientific Title

Respirator N95 masks to prevent the inhalation of urban air pollutants: a pilot intervention study in Hanoi, Vietnam

Acronym

01AV

Study objectives

To test if wearing the R95 Particulate Respirator face mask, produced by 3M reduces levels of pollution exposure biomarkers in 40 healthy volunteers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxford Tropical Research Ethics Committee approved on the 29th January 2009 (ref: 03/09)

Study design

Single centre open intervention cross-over study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Air pollution & respiratory problems

Interventions

The intervention consists of wearing a R95 particulate respirator (3M, 9900 series) on assigned days for a 2-week period. All volunteers start at the same time and will be randomly allocated to a specific scheme on when and when not to wear the study mask. Two mask-wearing sequences exist, being ABBA or BAAB, with the following routine:

- A. Two days activated carbon mask during transportation and working hours
- B. Two days with no mask

Urine samples will be taken at baseline and every three days of the study. Levels of polycyclic aromatic hydrocarbons metabolites in the urine will be tested. A daily diary will be kept detailing respiratory symptoms (sneezing, nasal congestion, nasal discharge, throat pain, cough, dyspnoea, eye irritation, other), comfort of the mask, general 'well being', fever, headache, nausea, motorbike accident, wearing glasses, food types consumed (any grilled food), time spent outside on the street.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Concentration of exhaust and smoking metabolites in urine, with 1-hydroxypyrene as the primary endpoint metabolite.

Outcomes will be measured at day 0 (baseline), day 4, day 7, day 11 and day 14.

Key secondary outcome(s)

Other metabolites in the urine including 1-hydroxynaphthalene, 2-hydroxynaphthalene, 2-hydroxyfluorene, 3-hydroxyfluorene, 9-hydroxyfluorene, 1-hydroxyphenanthrene, 2-hydroxyphenanthrene, 3-hydroxyphenanthrene, 4-hydroxyphenanthrene, Cotinine and Creatinine.

Outcomes will be measured at day 0 (baseline), day 4, day 7, day 11 and day 14.

Completion date

01/10/2009

Eligibility

Key inclusion criteria

Healthy male and female Vietnamese volunteers over 18 years of age

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Smoking tobacco
2. Cooking at home with biomass fuel
3. Not willing to stop eating grilled food during study period of 2 weeks
4. Home address is at a main city road
5. Not willing to wear a face mask
6. Type of work prohibits wearing a mask (e.g. regular conversation)
7. No direct access to mobile phone
8. Not able to read or write
9. Not able to complete the study for other reasons
10. Respirator mask does not fit (determined by fitness test)
11. No informed consent

Date of first enrolment

01/07/2009

Date of final enrolment

01/10/2009

Locations

Countries of recruitment

Viet Nam

Study participating centre

Oxford University Clinical Research Unit
Hanoi
Viet Nam
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Sponsor information

Organisation

University of Oxford (UK)

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (ref: 077078)

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	26/09/2012		Yes	No