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Respirator N95 masks to prevent the inhalation of urban air pollutants

Submission date	Recruitment status	[_] Prospectively registered
18/06/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/07/2013	Other	

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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/07/2009

Completion date
01/10/2009

Eligibility

Key inclusion criteria
Healthy male and female Vietnamese volunteers over 18 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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)

Sponsor details
Centre for Tropical Medicine
CCVTM
Churchill Hospital
Old Road
Headington
Oxford
England
United Kingdom
OX3 7LJ

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (ref: 077078)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/09/2012		Yes	No