Acute Health Effects Barbecue Fumes

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON48397

Source
ToetsingOnline

Brief title
nvt

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Lung function, respiratory health

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: (ultra)fine particles, Barbecue Fumes, Inflammation, Respiratory Health

Outcome measures

Primary outcome

Lungfunction (FVC, FEV1, PEF and MMEF)

Secondary outcome

Inflammatory markers and anti-oxidant defense system markers (nasal swab)

Respiratory symptoms.

Study description

Background summary

Barbecuing is a social get-together during which people can enjoy tasteful food. However, a study executed in China suggested that it also may result in health risks (2). While barbecuing, people will be exposed to a mix of gasses and particulate matter (PM). Although a great deal of research has been executed investigating the harmful effects of PM, a lot is still unknown regarding the health effects of complex mixtures like barbecue smoke. This research will therefore investigate the concentrations PM people will be exposed to, and which short term health effects will occur.

Study objective

The objectives are to study short-term changes in lung function in association with barbecue fumes in healthy volunteers aged 18 * 50 years. Secondly, changes in inflammatory markers and the antioxidant defence system using nasal swabs, and respiratory symptoms will be determined.

Study design

The study has a repeated measures design which will assess the acute health effects of healthy people exposed to barbecue fumes. 25 healthy, non-smoking volunteers will participate in two barbecue sessions, over the course of 3 months. Each person will participate in two sessions, one while barbecuing and one control session with identical procedures but no barbecue fumes. Both before and directly after the barbecue sessions lung function measurements and a questionnaire regarding respiratory symptoms will be executed. Furthermore, nasal swabs will be collected 4 times per barbecue sessions: before, immediately after, 4 hours later and the next morning. During both barbecue

sessions major air pollutants will be continuously measured, including particulate matter with an aerodynamic size of 2.5 micrometer, ultrafine particles and black carbon.
Whether the volunteers will participate first with the control- or exposure session will be determined through randomization. Furthermore, during the control barbecue session, the barbecue will be place downwinds from the volunteers, at a minimal distance of 100 meters.

Intervention

not applicable

Study burden and risks

The 25 volunteers will be asked to participate in two separate barbecue sessions over the course of three months. The total participation time will exist out of approximately 6.5 hours, including signing the informed consent form and 2 barbecue sessions. Lung function and the reporting of respiratory symptoms will be measured both before and directly after the barbecue sessions. Nasal swabs will be executed before, directly after, 4 hours later and the next morning. It is expected that two barbecue sessions including measurements, executed over the course of three months, will not alter the volunteers motivations to participate, because they will receive free dinner and breakfast. Furthermore, the researchers believe the risks of injury or negative effects on health, by participating in this study, are extremely low, as the volunteers will not get into direct contact with the barbecue. They will remain at a distance of 2 meters throughout the sessions. The participants will not benefit personally from participating in the study directly. However, they might learn about the potential health effects of exposure to barbecue fumes, potentially leading to behavioural changes in barbecue practice. For their participation time, the participants will receive a gift certificate of ¤25, once they completed the two barbecue sessions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy, non-smoking volunteers between 18-50 years old, living in Utrecht can participate. Both men and women will be included.

Exclusion criteria

exclusion criteria: being pregnant, smoker or living in a household with a smoker and having objections to eating meat. Furthermore, individuals who used anti-inflammatory medication in the last 12 months, or have a history of atopy, asthma, cardiovascular disease or COPD will be excluded.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-06-2019
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	24-05-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL69574.041.19