Measurement of Leakage of FFP2 Respirators and Surgical Masks in Human Volunteers

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Primary Objective: Assess the leakage of FFP2 respirators and surgical masks in human subjects using inhalable aerosols consisting of a solution of fluorescein in water.Secondary Objective(s): (a) Study the variability in total inward leakage of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON57244

Source
ToetsingOnline

Brief title
Facemask leakage testing

Condition

- Viral infectious disorders

Synonym
viral diseases, Viral infectious diseases

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Face masks, Fluorescein, Leakage

Outcome measures

Primary outcome

Total inward leakage, expressed as a percentage of the dose, based on the recovery of fluorescein tracer in saliva and urine following exposure to finely dispersed spray of inhalable aerosols with fluorescein dissolved in water.

Secondary outcome

Total inward leakage, expressed as a percentage of the dose, is based on the recovery of fluorescein tracer in the mask filters and skin wipes following exposure to finely dispersed spray of inhalable aerosols with fluorescein dissolved in water. The influence of facial hair length on total inward leakage in males will be analyzed by comparing leakage between different beard lengths (0 mm, 5 mm and 10 mm).

Study description

Background summary

In healthcare, respiratory protective equipment (RPE), especially face masks, has become indispensable to mitigate infection risk. The availability of good-quality RPE requires adequate efficacy testing. However, current testing protocols for RPE rely on the use of solid particles as a model for toxic exposures rather than liquid aerosols that carry airborne viruses. Additionally, there is limited understanding of interindividual differences in protection due to variations in face size and shape, as well as facial hair growth, which may change face seal fit and overall protection efficacy. This study aims to evaluate a new approach to assess the efficacy of face masks using fluorescein in water as a tracer to evaluate the total inward leakage of FFP2 respirators and surgical masks in a controlled laboratory study using

inhalable liquid aerosols.

Study objective

Primary Objective: Assess the leakage of FFP2 respirators and surgical masks in human subjects using inhalable aerosols consisting of a solution of fluorescein in water.
Secondary Objective(s): (a) Study the variability in total inward leakage of FFP2 respirators and surgical masks in a small group of males and females, and (b) Evaluate the effect of facial hair growth on the total inward leakage in males.

Study design

In a controlled laboratory setting, healthy subjects will be exposed to a finely dispersed spray of inhalable aerosols containing a fluorescein solution in water to quantify face mask leakage.

Intervention

Exposure to a finely dispersed spray of aerosols containing 10% fluorescein sodium in a 5 mL water solution, without and while wearing an FFP2 respirator or surgical mask.

Study burden and risks

Human subjects will be asked to participate in three or five visits lasting two hours each. These events involve the nebulization of a fluorescein solution while wearing either an FFP2 respirator or surgical mask. Human subjects will be asked to complete a questionnaire regarding general information and to provide saliva and urine samples. The risk of this study is negligible, as the exposure level will not exceed that typically used in medical diagnostic procedures with fluorescein. There are no benefits for human subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a human subject must meet all of the following criteria:
- Healthy males and females
- Aged 18-60 years at the time of inclusion
- European (Caucasian) or Asian descent
- No history of atopic disorders
- No facial hair growth or shaved.

Exclusion criteria

A potential human subject who meets any of the following criteria will be excluded from participation in this study:
- Unable to complete the informed consent procedure independently
- Individuals with medical and/or cosmetic surgery that altered the form of their face
- Individuals who are medically unfit to wear a standard face mask (e.g., due to airway diseases such as COPD or asthma, or skin reaction)
- Individuals with a history of exposure to fluorescein. This includes intravenous administration of fluorescein for imaging purposes (such as fluorescein angiography) or local administration of fluorescein in the eye for corneal damage diagnostics
- Pregnancy or (partner) intention to become pregnant during the study period
- Male with facial hair growth unwilling to shave it (beards and/or

moustaches).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	27-01-2025
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL87018.091.24