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On the effectiveness of ion-air disinfection for the prevention of upper respiratory tract infections

Submission date 19/10/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/11/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/04/2024	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Upper respiratory tract infections (URTIs) are among the most common diseases worldwide and are of major socioeconomic importance because of the direct and indirect costs of illness. Although URTIs are often self-limiting and usually do not progress severely, symptoms can significantly affect an individual's quality of life and productivity. Considering aerosols play a major role in the transmission of infections, the purpose of this study is to investigate whether the use of air-ion disinfection can reduce or alleviate URTIs in a test group of 150 subjects in the workplace over a period of 5 months, thus improving workability and, consequently, productivity in companies as an effective preventive health measure. From a public health and business perspective, it is important to establish a solid evidence base.

Who can participate?
Adult employees aged between 18-65 years old from industrial)companies in Upper Austria and Salzburg who have equipped their workplace with a CUBUSAN air purification device or a dummy device

What does the study involve?
The study design is an interventional, double-blind, randomized controlled trial at one center during the peak infection season in the fall/winter of 2022/23. Sample size n= 150. Two groups will be formed: 73 with an ion-air purification device (intervention group) at their workplace, and 77 with a dummy device (control group). The results of an upper respiratory symptom questionnaire will be evaluated as the primary outcome parameter. A health check will be performed every two months with specific questionnaires on health-related quality of life, workability, physical activity, recovery/stress, sleep, and household composition. In addition, Immunological and inflammatory surrogate parameters are measured by saliva samples. The Chester-Step-Test is used to evaluate aerobic endurance performance. The intervention also includes a one-time point measurement at the end of the study of several environmental parameters.

What are the possible benefits and risks of participating?
Potentially, the occurrence of URTIs during the intervention may be reduced. Upon completion of all assessments, participants will receive a compensation of 120 EUR for their participation in all health checks and ongoing completion of questionnaires. The risks associated with this intervention are very low. A potential risk could arise during the execution of the Chester-Step-Test, which is used to determine maximal oxygen levels. Therefore, we have chosen a modified test that can be terminated after each level of exertion.

Where is the study run from?
Paracelsus Medical University (Austria)

When is the study starting and how long is it expected to run for?
May 2022 to March 2023

Who is funding the study?
1. Paracelsus Medical University (Austria)
2. Wintersteiger AG (Austria)

Who is the main contact?
Mrs Renate Weisböck-Erdheim, renate.erdheim@pmu.ac.at (Austria)

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Healthy workplace: lower infection rate and milder upper respiratory tract infections (URTIs) through ion-air-disinfection

Acronym
AirDisP_URTI

Study objectives
As aerosols play an essential role in the transmission of infections, the aim of this study is to investigate whether the use of ion air disinfection can reduce the number of upper respiratory tract infections (URTIs) in a population of 150 subjects at their workplace over a period of 5 months and thus improve quality of life and consequently workability in companies as an effective preventive health measure. Thus, from a public health and a health economics point of view, it is relevant to establish a solid evidence base.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/10/2022, Paracelsus Medical University Ethics Committee (Strubergasse 21, Salzburg, 5020, Austria; +43 699 144 200 18; ethikkommission@pmu.ac.at), ref: WS2223-0011-0058

Study design
Single-centre interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Workplace

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
URTI prevention in working people through ion air disinfection

Interventions
The study design is an interventional, double-blind, randomized controlled trial at one center during the peak infection season in the fall/winter of 2022/23. Sample size n= 150. The randomization in this study will be conducted through third-party involvement using a device placement procedure at the participants' workplace. The aim of randomization is to ensure that participants are assigned randomly to one of two experimental groups, while the allocation is blinded for both the researchers and participants, to avoid potential biases or prejudices. Two groups will be formed: 73 with an ion-air purification device (intervention group) at their workplace, and 77 with a dummy device (control group).

The results of the questionnaire WURSS-21 (Wisconsin Upper Respiratory Symptom Survey) will be evaluated as the primary outcome parameter, as it assesses symptom severity and functional impact of common cold and flu-like illnesses.

A health check will be performed every two months with specific questionnaires on health-related quality of life, workability, physical activity, recovery/stress, sleep, and household composition. In addition, immunological and inflammatory surrogate parameters are measured by saliva samples. Saliva is used because it is easier to sample and thus has better compliance from the participants, and saliva analyses in the laboratory are well established.

The Chester-Step-Test is used to evaluate aerobic endurance performance.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cubusan Air Purifier (WINTERSTEIGER AG, Austria) based on Sterex plasma technology for indoor air disinfection.

Primary outcome measure
Occurrence and severity of URTIs measured using the Wisconsin Upper Respiratory Symptom Survey (WURSS-21) online each time a disease symptom occurs and until it has completely resolved

Secondary outcome measures
The following secondary outcomes will be measured bimonthly at each of the three timepoints (November 2022, January 2023 and March 2023) using questionnaires or the specified measurement instruments:
1. The workability of employees measured using the Work Ability Index (WAI)
2. Health-Related Quality of Life measured using 3 well-established questionnaires:
2.1. 12-Item Short Form Survey (SF-12)
2.2. Intercultural Quality of Life Comic (IQoLC)
2.3. The World Health Organisation- Five Well-Being Index (WHO-5)
3. Physical Activity Levels measured using the Physical Activity Level two-question (PAL-2Q) questionnaire
4. Current states of load and the states of recovery measured using the Recovery-Stress Questionnaires RESTQ-EBF

The following four molecular surrogate parameters for infection and immunity are measured from saliva samples using Luminex-ELISA. Saliva samples will be taken bimonthly in November 2022, January 2023, and March 2023:
1. Salivary C-reactive protein (CRP)
2. Interleukin-6 (IL-6)
3. Interleukin-10 (IL-10)
4. Salivary Immunoglobulin A (sIgA)

The following environmental parameters are measured at a one-time point at the end of the study:
1. Negative ions measured using the AiC2. The Air Ion Counter 2 is a handheld meter designed to measure ion density– the number of ions per cubic centimetre (ions/cc) in air. It measures this number separately for positive and negative ions (+ and – ions are usually present simultaneously).
2. Temperature, Relative Humidity, Carbon dioxide and air velocity measured with Testo 400 Universal Indoor Air Quality Instrument
3. The following particulate matter data PM1, PM2.5, PM4, PM10 and dCn (P/cm3) measured using Fidas Frog, a portable fine dust measurement device

4. PM0.3, LDSA and Number parameter measured using Partector 2 - Handheld Nanoparticle Detector
5. Airborne microbial contamination measured using the HYCON Airsampler and TSM agar strips for the determination of colony forming units (CFU) according to an established method of the Institute of Ecomedicine

Overall study start date
02/05/2022

Completion date
27/03/2023

Eligibility

Key inclusion criteria
Inclusion criteria:
1. Adults 18-65 years old who have their workplace equipped with CUBUSAN air purification devices and dummy devices
2. Ability to exercise according to the Physical Activity Readiness Questionnaire (PAR-Q) as the basis for the Chester Step Test cardiorespiratory fitness survey

Participant type(s)
Employee

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
230

Total final enrolment
230

Key exclusion criteria
1. Immunosuppression and genetic immunodeficiency disorders (primary immunodeficiency syndromes)
2. Immunodeficiency disorders
3. Severe respiratory disease requiring oxygen supplementation
4. Acute and untreated mental illnesses
5. Uncontrolled hypertension - systole ≥ 180mmHg; diastole ≥ 100mmHg
6. Active infectious diseases

7. Malignant neoplastic disease. No treatment within the last 5 years
8. Arteriosclerotic event <6 months prior to enrolment (e.g., myocardial infarction, stroke, TIA).
9. Heart failure
10. Renal insufficiency
11. Use of >5mg/d prednisone, colchicine, imuran, methodrexate, azathioprine, cyclophosphamide, cyclosporine, or interferon preparations
12. Depression
13. Alcohol abuse, drug abuse, smoking > 20 cigarettes/day.

Date of first enrolment
29/10/2022

Date of final enrolment
09/11/2022

Locations

Countries of recruitment
Austria

Study participating centre
Aerztekammer Oberoesterreich
Dinghoferstraße 4
Linz
Austria
4010

Study participating centre
B&R Industrial Automation GmbH
B&R Straße 1
Eggelsberg
Austria
5142

Study participating centre
B & R Standort Salzburg
Wasserfeldstraße 15
Salzburg
Austria
5020

Study participating centre

Ebner Industrieofenbau
Ebner-Platz 1
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4060

Study participating centre
Raiffeisenlandesbank Oberoesterreich
Europaplatz 1a
Linz
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4020

Sponsor information

Organisation
Paracelsus Medical University

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Sponsor type
University/education

Website
https://www.pmu.ac.at/

ROR
https://ror.org/03z3mg085

Funder(s)

Funder type
Industry

Funder Name
Paracelsus Medical University

Funder Name
Wintersteiger AG

Results and Publications

Publication and dissemination plan
Planned publication in the high-impact and peer-reviewed Buildings journal

Intention to publish date
30/05/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Arnulf Hartl, arnulf.hartl@pmu.ac.at.
• The type of data that will be shared: Pseudonymized data in SPSS-format.
• Timing for availability: After acceptance of the proposed paper from 2024.
• Whether consent from participants was required and obtained: In their informed consent, the participants agreed that their pseudonymized data may be passed on for scientific purposes.
• Comments on data anonymization: The anonymization of the personal data was implemented by means of a 5-digit numerical code.
• Any ethical or legal restrictions: no
• Any additional comments: no

IPD sharing plan summary
Available on request