Integrated environmental and Integrated environmental and clinical surveillance for the prevention of acute respiratory infections (ARIs) in closed settings and vulnerable communities (Stell-ARI)

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Study Ongoing

Administrative details

EU PAS number

EUPAS106190

Study ID

106191

DARWIN EU® study

No

Study countries

Italy

Study description

The infectious diseases surveillance is a key element of early warning systems and preparedness for current and future threats. Acute respiratory viral infections (VARI) cause substantial disease burden, as highlighted not only by COVID-19, but also by other viruses such as influenza and respiratory syncytial virus. These viruses spread mainly in community settings (i.e. schools) and in closed settings characterized by vulnerability of physical (i.e. long-term care facilities) and socioeconomic (i.e. prisons) origin. Environmental characteristics, in particular air quality, and working/living conditions, represent important determinants of diseases. Moreover, the Wastewater Based Epidemiology, extensively used for SARS-CoV2, is now recognized very useful as monitoring and early warning tool. Data coming from both clinical and environmental surveillance of infections are essential to assess the risk, to plan prevention measures and to evaluate their efficacy, but they are affected by bias that could be reduced by integrating them. Funded by the Next Generation EU, our project will consist in creating and testing an Environmental and Clinical Integrated Surveillance System of VARIs and their determinants for communities, using clinical surveillance, environmental monitoring (air, surface and wastewater) and data collection on environmental and behavioral risk factors. In the initial phase of the project, the data collection tools will be designed and validated: questionnaires for symptoms and personal risk factors, separately for the different settings and subjects (e.g. residents and workers), methods for collection and analysis of clinical (swabs) and environmental (air, surfaces and wastewater) samples, integrated database. Furtherly, these tools will be applied in field conditions, data analysis will be performed and, through integration of all information, models will be designed for early warning and for Quantitative Microbial Risk Assessment (QMRA).

Study status

Ongoing

Research institutions and networks

Institutions

University of Pisa

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Institution

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/08/2022

Actual: 29/08/2022

Study start date

Planned: 02/10/2023

Actual: 10/10/2023

Date of final study report
Planned: 31/01/2026

Sources of funding

- Other

More details on funding

Ministero dell'Università e della Ricerca with NextGenerationEU funds

Study protocol

Stell-ARI Protocol.pdf (203.2 KB)

Stell-ARI_Protocol_FINAL 07_09_2023.pdf (513.17 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Method development or testing

Data collection methods:

Primary data collection

Main study objective:

The aim of this study is to create an integrated clinical and environmental surveillance system of VARIs and its determinants in community settings in order to plan prevention strategies and interventions to minimize the spread of infections.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Environmental monitoring, Active surveillance

Study drug and medical condition

Medical condition to be studied

COVID-19

SARS-CoV-2 test

Influenza

Adenovirus infection

Respiratory syncytial virus infection

Environmental exposure

Influenza like illness

Additional medical condition(s)

Environmental characteristics: general characteristics of the facility, daily activities performed, hygiene rules followed in the facility. Individual characteristics: general characteristics of the individual, general pathology of the subject including respiratory and allergic pathology, vaccination status, exposure to risk factors, socio-economic factors, acute pathology during the study period.

Population studied

Age groups

- Children (2 to < 12 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

500

Study design details

Outcomes

Integration of clinical, behavioural and environmental data to develop early warning and risk prediction models that can be transferred to similar communities at the regional/national/international levels. 1. Establishment of sentinel clinical surveillance and risk factors for VARI in selected closed environments for the detection of specific respiratory diseases and their evolution. 2. Establishment of sentinel environmental surveillance in closed environments on the basis of environmental parameters, indoor air quality monitoring, microbiological monitoring of wastewater.

Data analysis plan

Subject characteristics will be described by means of medians and interquartile ranges for numerical variables and absolute frequencies and percentages for categorical variables. The time course of the environmental variables will be represented by means of graphical displays and spline regression models will be used to estimate their time course. The association between infections detected by nasopharyngeal swabs/questionnaires and exposure factors will be assessed by means of logistic regression models that take possible confounders into account. QMRA models will be developed, and Monte Carlo Analysis will be applied through Vensim software. The relationship between ARI incidence and environmental data will be investigated by means of time series regression models. Analyses will encompass the entire dataset or be stratified based on different settings. Statistical tests will be two-sided with a significance level set at $\alpha = 0.05$. Data will be analysed with the statistical software R.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Environmental data: chemical and microbiological analysis of surfaces, air and wastewater samples

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No