REspiratory Syncytial virus Consortium in EUrope (RESCEU) study: Defining the burden of disease of Respiratory Syncytial Virus in older adults in Europe.

Published: 13-07-2017
Last updated: 12-04-2024

To determine the burden of disease due to RSV in older adults.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON45431

Source
ToetsingOnline

Brief title
Burden of disease of RSV in older adults

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
RSV-infection, RS-virus infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Innovative Medicine Initiative (IMI):

EU/Horizon2020 en EFPIA (European Federation of Pharmaceutical Industries and Associations)

Intervention

Keyword: Burden of disease, Older adults, Respiratory infection, RSV (Respiratory Syncytial Virus)

Outcome measures

Primary outcome

Primary Objective:

* To estimate the incidence of RSV infection-associated ARTI, RSV MA-ARTI and

RSV hospitalization in older adults.

Secondary outcome

Secondary objectives:

* To estimate the rate of all-cause MA (inpatient or outpatient) ARTI and

related medical complications (exacerbations of chronic conditions, acute

cardiovascular events).

* To estimate the RSV-associated and all-cause mortality.

* To estimate health care costs, health care resource use, interruption of

normal activities, and Health Related Quality of Life (HRQoL) in RSV-associated

and all-cause MA (inpatient or outpatient) ARTI patients.

* To estimate the incidence of RSV-related secondary bacterial pneumonia events

and their association with antibiotic use within 21 days after onset of RSV

infection.

* To collect clinical samples for biomarker analysis.

* To examine the incidence of other respiratory pathogens associated with all

MA-ARTI

* To estimate the proportion of acute viral ARTI attributable to RSV.

* To estimate important risk factors for RSV infections (by severity and

healthcare utilizations).

* To determine change in frailty over the course of the study.

Study description

Background summary

The REspiratory Syncytial virus Consortium in EUrope (RESCEU) is an Innovative Medicine Initiative (IMI) funded by the EU and EFPIA under the H2020 framework to define and understand the burden of disease caused by human respiratory syncytial virus (RSV) infection.
RSV causes severe disease in individuals at the extremes of the age spectrum and in high risk groups such as patients with COPD. Published data on the burden of disease of RSV in the elderly population is mainly from research groups in the United States and focuses mainly on hospitalized patients. The estimated burden of disease in older adults is comparable with non-pandemic influenza. These estimates were based on limited data and there is a substantial gap in knowledge on morbidity and associated healthcare and social costs in Europe. New vaccines and therapeutics against RSV are in development and could soon be available on the European market.
RESCEU will deliver knowledge of the incidence and burden of RSV disease in young children and older adults in Europe, which is essential for stakeholders (governments, etc.) to take decisions about prophylaxis and treatment.

Study objective

To determine the burden of disease due to RSV in older adults.

Study design

This will be a multi-country, multicenter, prospective, observational cohort study.
In the Netherlands the study will be monocenter (UMCU) with the collaboration of general practitioners offices who function as recruitment centers.

Study burden and risks

The burden of study participation will consist of the following:

Sample collection:

For all participants:
- Venepuncture: 2× 60ml (start and end of the RSV season)
- Nasopharyngeal swab: 2× (start and end of the RSV season)

Only for participants with an acute respiratory tract infection:
- Nasopharyngeal swab: 2× at each new episode of a respiratory infection (POCT/PCR)
- Oropharyngeal swab: 1× at each new episode of a respiratory infection

Only for participants with a RSV ALRI:
- Venepuncture: 1× 60ml at the moment of acute infection, 1× 30ml 1-2 weeks after the start of acute RSV infection
- Nasopharyngeal swab: 1× at the moment of acute infection, 1× 1-2 weeks after the start of acute RSV infection

Questionnaires:

For all participants:
- Baseline questionnaire
- Quality of life baseline meassurement (2× at inclusion and after 1 year)
- 1-year questionnaire
- During the RSV season (October up till May); weekly questionnaire with one question: are there respiratory symptoms?

Only in participants who experience respiratory symptoms during the RSV season:
- Diary on respiratory symptoms (daily until the end of the infection)
- Quality of life questionnaire (daily until the end of the infection)
- End of infection questionnaire when the symptoms are gone.

Although there is a risk of minor complications such as bruising following a blood draw or epistaxis after a nasopharyngeal swab, there is no risk of severe complications. Therefore we believe that the burden of participation is acceptable in the light of the gained knowledge that will result from this research. Information from this study can inform us about the burden of disease in this population and may help us treat or prevent severe RSV infections in the future.

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

- Male and female adults *60 years of age
- Willing and able to give written informed consent
- Willing and able to adhere to protocol-specified procedures

Exclusion criteria

- Current alcohol or drug abuse or history of unsuccessfully treated alcohol or drug abuse within the past year
- Unable to perform the study procedures
- Dementia
- Life expectancy less than 1 year
- Any known or suspected immunosuppressive condition, acquired or congenital, as determined by history and/or physical examination (a more detailed description/list can be found in appendix 3 of the study protocol).
- Chronic administration (defined as more than 14 continuous days) of immunosuppressants or other immune-modifying drugs within 6 months prior to study participation. The use of topical, inhaled, and nasal glucocorticoids will be permitted (a more detailed description/list

can be found in appendix 3 of the study protocol).
- Previous participation in this study or in a RSV interventional trial (vaccine, antivirals)
- Planned leave/holiday during the winter season of more than 1 month in total.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2017
Enrollment:	333
Type:	Actual

Ethics review

Approved WMO

Date:	13-07-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	14-08-2019
Application type:	Amendment
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	NL60910.041.17

Study results

Date completed: 16-07-2019

Actual enrolment: 356

Summary results
Trial is onging in other countries