Study on household Transmission using sAliva RSV tests (STARS-I) - a pilot study

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A pilot study to understand the transmission dynamics of RSV in households and potential reduction of viral transmission.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56918

Source
ToetsingOnline

Brief title
STARS-I

Condition

- Viral infectious disorders

Synonym
respiratory tract infection, RSV infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: bedrijf,Sanofi Pasteur SA

Intervention

Keyword: Household transmission, Infants, Respiratory Syncytial Virus (RSV), Saliva

Outcome measures

Primary outcome

The primary outcomes are the probability of introduction of RSV into the household by type of household member and probability of transmission between household members. To determine the probability of types of household members to introduce RSV in the household, we will identify the index case of each household RSV episode as the first household member to be infected. To determine the probability of transmission between household members, we will reconstruct the chain of transmission using RSV testing results, information from the questionnaires and a chain binomial model. To capture all RSV infections, household members will be asked to take saliva samples twice per week of follow-up. The presence of RSV in samples will be ascertained by PCR.

Secondary outcome

1. The annual incidence of RSV infection in households with young children
2. The proportion of asymptomatic RSV cases among all RSV infections in adults and children
3. The rate of secondary RSV infections within the same household
4. The duration of RSV positivity
5. The delay between the first positive sample of two generations of cases
6. The secondary attack rate in grandparents who visit the household on a weekly base

Study description

Background summary

Respiratory syncytial virus (RSV) causes a large burden, especially in infants and older adults. New preventive strategies have recently been approved by the European Medicines Agency to protect infants against severe RSV disease. These strategies aim to decrease the burden of RSV but are not expected to limit transmission. However, live-attenuated RSV vaccines targeted at older children are currently at various stages of clinical development. As having older siblings has consistently been found to be associated with an increased risk of RSV infections, it has been hypothesized that older children serve as reservoirs for RSV transmission. If this is the case, childhood vaccines have a high potential to decrease RSV transmission and provide indirect protection to high-risk groups. Understanding the dynamics of RSV transmissions in households is important to assess the potential public health interest of future RSV childhood vaccines against RSV. This household transmission study aims to follow families with infants during their first RSV season to understand the RSV transmission dynamics in households and estimate the role of children in introducing RSV in the household.

Study objective

A pilot study to understand the transmission dynamics of RSV in households and potential reduction of viral transmission.

Study design

Monocenter prospective observational household study.

Study burden and risks

In households that agree to participate in the study, parents will be asked to complete a questionnaire at inclusion. During the winter season, all individuals living in the household will be asked to take a saliva sample and to complete a short (online) questionnaire on respiratory symptoms twice a week. Parents will be trained to take their own samples (by spitting into an tube) and to sample their children (in young children by means of a pipet to obtain sample from their mouth), if needed, with assistance from a member of the study team. The advantage of using saliva samples instead of nasopharyngeal samples is minimizing discomfort. Regular home visits will be scheduled to assist with sample collection, bring new study materials, pick up samples and monitor follow-up. There is minimal risk associated with this study. None of the study procedures is associated with any risk of serious complications. All the study data will be coded to safeguard participants' privacy.
There is no direct benefit for the subjects participating in this study. However, the results will improve our understanding of RSV transmission in households. This is important information to evaluate if vaccinating older

children is likely to decrease RSV transmission and provide indirect protection to high-risk groups.
The expected impact of this pilot study is that it will generate solid household transmission data in the Netherlands. In addition, this pilot study will form the basis for a larger confirmatory study which will allow us to understand the potential indirect beneficial impact of RSV vaccination of children beyond the first year of life.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

- Be part of a household with at least 1 child <6 months and one child <4 years of age at the start of the RSV season (1 October or earlier if the RSV season starts earlier).
- Willing and able to give informed consent for themselves and their children.
- Willing to adhere to the study specific procedures.
- Be part of a household in which all other household members gave consent to participate in the study.

Optional
Grandparents (age >60 years) will be included when visiting the household at least once a week for at least 4 hours (pe regular babysitting while parents go to work) during the whole study period.

Exclusion criteria

- Clinically significant primary or secondary immunodeficiency.
- Having a household member who does not participate or who intend to be away from the household for >1 month during the study period.
- Not able to communicate in Dutch or English.
- Any medical condition for which it is foreseen that the household member will be hospitalized >7 days during the study period.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-09-2024
Enrollment:	300

Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-07-2024
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-09-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NL86960.041.24