The RSV GOLD III study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24263

Source
NTR

Brief title
The RSV GOLD III study

Health condition

Respiratory syncytial virus and Influenza virus

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Bill & Melinda Gates Foundation

Intervention

Outcome measures

Primary outcome

To describe the clinical, demographic and socioeconomic characteristics of RSV-positive children under 2 years of age who have been admitted with suspected RSV infection at ICUs or HDUs in GAVI eligible countries.

Secondary outcome

-

Study description

Background summary

The main objective of this study is to describe the clinical, demographic and socioeconomic characteristics of RSV-positive children under 2 years of age who have been admitted with suspected RSV at intensive care units (ICUs) and high dependency units (HDUs) in GAVI eligible countries. One of the secondary objectives of this study is to collect similar data on influenza infection in the target population as a comparator disease. We will perform an international, prospective, observational multicenter study in 10 countries at 10 ICUs or HDUs during 2 RSV seasons. Children who meet the inclusion criteria will be tested for RSV (all 10 sites) and influenza (at 3 sites). In addition, the study will be performed in 2 pediatric ICUs from the Netherlands to allow for a comparison with a high-income country. A molecular point-of-care (POC) device will be provided by University Medical Centre Utrecht (UMCU) to all LMIC study sites. We will collect clinical and demographic characteristics of tested children using a questionnaire.

Study objective

This study will collect data describing the clinical, demographic and socioeconomic characteristics of individual RSV-positive children under 2 years of age who have been admitted with suspected RSV infection at ICUs or HDUs in GAVI eligible countries.

Study design

• March 15, 2021: Start of data collection (first patient in).
• September 1, 2023: End of data collection.
• Methods for data collection: point-of-care RSV and influenza testing, for RSV and influenza-positive patients filling out case report form and parental questionnaire.

Intervention

POC RSV test and 2 questionnaires

Contacts

Public
UMC Utrecht
Yvette Löwensteyn

0031611845371
Scientific
UMC Utrecht

Yvette Löwensteyn

0031611845371

Eligibility criteria

Inclusion criteria

For this study, 2 groups (A and B) are distinguished:
• Group A: Suspected RSV (10 study sites): Children under 2 years of age admitted to an ICU or HDU who meet the WHO case definition “extended SARI”. All children will be tested for RSV. At 3 study sites, children from group A will also be tested for influenza.
• Group B: Non-suspected RSV (3 study sites; 1 site per country): To determine whether the case definition “extended SARI” is sufficiently sensitive for detecting children with severe RSV infection, we will also test children for RSV who do not meet the case definition at 3 study sites: children under 2 years of age admitted to an ICU or HDU who do not meet the WHO case definition “extended SARI”.

Exclusion criteria

Subjects can only participate when RSV or influenza samples are collected while admitted to the ICU or HDU at participating study sites. Subjects <4 days of age will be excluded.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	15-11-2020
Enrollment:	4000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	27-05-2021
Application type:	First submission

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
NTR-new	NL9519
Other	METC UMCU : METC 20-536

Study results

Summary results
not applicable