The RSV GOLD III study

Gepubliceerd: 27-05-2021 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24263

Bron
NTR

Verkorte titel
The RSV GOLD III study

Aandoening

Respiratory syncytial virus and Influenza virus

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: Bill & Melinda Gates Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

• 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.

Onderzoeksproduct en/of interventie

POC RSV test and 2 questionnaires

Contactpersonen

Publiek

UMC Utrecht
Yvette Löwensteyn

0031611845371

Wetenschappelijk

UMC Utrecht
Yvette Löwensteyn

0031611845371

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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”.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-11-2020
Aantal proefpersonen:	4000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	27-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9519
Ander register	METC UMCU : METC 20-536

Resultaten

Samenvatting resultaten
not applicable