Multi-centre EuRopean study of Major Infectious Disease Syndromes

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1) To estimate the proportion of children aged * 6 months with sepsis-like syndrome (SLS) which is attributable to Enterovirus (EV) or Human Parechovirus (HPeV) infection.2) To estimate the proportions of cases of ARI in children aged 0 to 5 years...

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

Summary

ID

NL-OMON43251

Source
ToetsingOnline

Brief title
PREPARE PED-MERMAIDS

Condition

- Viral infectious disorders

Synonym
epidemics, infectious diseases

Research involving
Human

Sponsors and support

Primary sponsor: Fondazione PENTA onlus
Source(s) of monetary or material Support: EU

Intervention

Keyword: Acute Respiratory Infections, pediatrics, Sepsis Like Syndrome, virology

Outcome measures

Primary outcome

The overall primary objective is to estimate the proportion of cases of SLS and

ARI attributable to specific pathogens.

* To estimate the proportion of cases of infants * 6 months old hospitalised

with sepsis-like syndrome which are attributable to Enterovirus (EV) or Human

Parechovirus (HPeV) infection.

* To estimate the proportions of cases of children 0 to 5 years old

hospitalised with ARI which are attributable to respiratory syncytial virus

(RSV), influenza virus, human rhinovirus (HRV) or S. pneumoniae infection.

Secondary outcome

please see protocol

Study description

Background summary

SLS and ARI are frequent causes of hospitalisation in infants and young children, and pose a risk of severe outcomes and potentially also of long-term complications. Both can be caused by pathogens with epidemic potential, importantly EV and HPeV for SLS, and RSV, influenza virus, HRV, S. pneumoniae for ARI. A better understanding of the role of these pathogens can inform diagnostics, surveillance and management in this vulnerable age group as well as prevention and outbreak response management.
The overall aim of this observational, case-control study is to prospectively

study the aetiology, diagnostics, clinical management, impact and outcomes across Europe of:
1) Community acquired sepsis-like syndrome in infants (*6 months old) requiring hospitalisation.
2) Community acquired acute respiratory tract infection in children (0-5 years old) requiring hospitalisation.
The study will focus on specific pathogens known to be aetiological agents of the two syndromes of interest (SLS and ARI). The study will also contribute to capacity building within the paediatric PREPARE network aimed at establishing early and robust European responses to (re-)emerging infections including rapid identification, control and research responses.

Study objective

1) To estimate the proportion of children aged * 6 months with sepsis-like syndrome (SLS) which is attributable to Enterovirus (EV) or Human Parechovirus (HPeV) infection.

2) To estimate the proportions of cases of ARI in children aged 0 to 5 years old attributable to respiratory syncytial virus (RSV), influenza virus, human rhinovirus (HRV) infection or S. pneumoniae.

Study design

prospective case-control study

Study burden and risks

Research samples will be collected with routine samples whenever possible to minimise patient discomfort.
In addition to research samples, in some cases residuals of clinical samples may be collected (e.g. CSF).

Any other microbiological samples taken as part of diagnostics and routine care by the local clinical teams, including blood cultures, will be analysed locally as per standard care and diagnostic work up. The results of these local tests will also be recorded in the CRF.

Clinical observations, treatments and medical interventions will be recorded in the CRF on admission (Day 0), and for cases until discharge, death or day 30 of hospitalisation (whichever comes first).

Follow-up visits are not planned for most cases or controls, except for a subgroup of 40 SLS cases who will be invited back for developmental assessments

at 12 months of age.

Contacts

Public
Fondazione PENTA onlus

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. SLS group:
Children (<6 months old) admitted to hospital with sepsis-like syndrome
2. ARI group:
Children (0 to 5 years old) admitted to hospital with acute respiratory tract infection
3. healthy controls:
children in the age of 0-5 years without a medical history or current symptoms

Exclusion criteria

SLS/ARI groep:
aetiology other than infection; immunocompromised patient, presence of complex chronic comorbidities; <3kg and/or corrected gestational age <37 weeks
healthy controls:
presence of comorbidities

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	27
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-09-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL57433.078.16