An Observational Study of the Causes, Management, and Outcomes of Community-acquired Sepsis and Severe Sepsis in Southeast Asia

Sepsis Study Team

Background

- Bacterial and viral infectious diseases are still the leading cause of death in Southeast Asia
- Sepsis is defined as the body's response to infectious diseases, including bacterial and viral causes.
- Patients with severe infectious diseases may not present with fever, and infectious causes may be overlooked by physicians.
- On the other hand, it is common for patients who are diagnosed with sepsis on admission to later have a confirmed non-infectious diagnosis.

Objectives

Primary objective

To determine the causes of community-acquired sepsis and severe sepsis in adult and pediatric subjects across Southeast Asia.

Secondary objective

- To define the current acute management (within the first 48 hours after admission) of subjects presenting with community-acquired sepsis and severe sepsis. This will provide the basis for designing practical interventions to reduce the mortality of subjects with sepsis and severe sepsis in the future.
- To define the clinical outcomes of community-acquired sepsis and severe sepsis in Southeast Asia.

Study Design

Sample size

- 2,250 patients with sepsis or severe sepsis patients
- Each country (Thailand, Vietnam, and Indonesia) will enroll 750 subjects. 3 participating sites in Indonesia are RSUPN dr Cipto Mangunkusumo, RSUP dr Wahidin Sudirohusodo, and RSUP dr Sardjito.
- Indonesia will recruit 375 adults and 375 children

Accrual Period

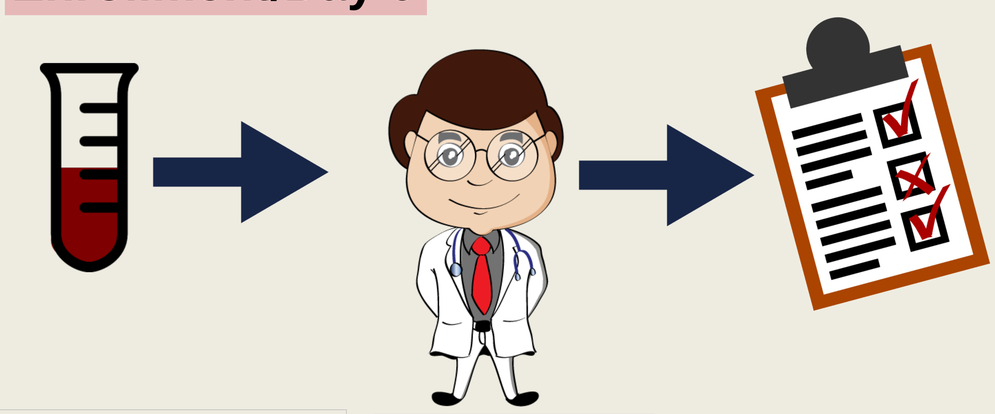
Up to 2 years

Laboratory Testing

Disease	Test	Specimen
Tests to be performed in Blood Culture Negative cases [estimated to be 90% of subjects]		
Common bacterial infection	PCR 16s	Blood
Tests to be performed on patients with CNS symptoms where CSF is available [estimated to be 10% of subjects]		
Bacterial and fungal infection	Culture	CSF
M tuberculosis	AFB Slides	
Neisseria meningitis Streptococcus pneumonia	PCR 4-plex	CSF
Herpes simplex virus Varicella Zoster virus	PCR 2-plex	CSF
Dengue virus	PCR	CSF
Japanese Encephalitis virus	IgM ELISA	CSF
Tests to be performed on subjects with respiratory symptoms [estimated to be 10% of subjects]		
M tuberculosis	AFB Slides	Respiratory specimen
14 respiratory virus (including influenza)	PCR 14-plex	Nasal swab + Pharyngeal swab
Mycoplasma pneumoniae	PCR 5-plex	Nasal swab + Pharyngeal swab
Tests to be performed on subjects with diarrheal symptoms [estimated to be 20% of subjects]		
General bacterial infection	Stool culture	Stool
Rotavirus	ELISA or PCR	Stool
Tests to be performed in cases where the cause of sepsis/severe sepsis is unknown [estimated to be 80% of subjects]		
Leptospirosis	PCR & MAT	Blood
Scrub Thypus	PCR & IFA	Blood
Murine Thypus	PCR & IFA	Blood
Hanta virus	PCR	Blood
Spotted fever group	PCR	Blood

Study Flow

Enrollment/Day 0



Blood Sample Collection for:
- Research tests
- Rapid Diagnostic tests
- EDTA for DNA (Optional for adults only)
- CSF, respiratory specimen, urine, stool (if available)

Monitor if AE/SAE/UP
Occurred within 48 hours

Review Medical Records:
- Medical History
- Basic Physical Exam
- Vital Signs
- Any Investigations
- Treatments received from the primary hospital (if available) to the time of admission to the ER to the time of enrollment

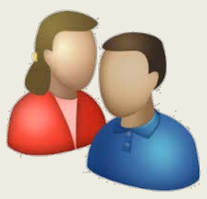
1st Follow-up (Day 14-20)

Blood collection for research specific tests:
Adult and Children ≥ 7 years old: 10 mL (8-12 mL)
Children ≥ 3 and < 7 years old: 5 mL (4-6 mL)
Children ≥ 30 days and < 3 years old: 3 mL (2-4 mL)

Complete subject follow-up visit log and complete CRF

Follow-up if AE/SAE/UP occurred within 48 hours

2nd Follow-up/End of Study (Day 28-35)



Visit at ward, phone interview or home visit
- Survival Questionnaire
- Clinical Outcome

CRF Completion:
FINAL

Partners

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