

# Pathophysiological aspects of hyperglycemia in children with meningococcal sepsis and septic shock

<b>Submission date</b> 22/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/07/2010	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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**Contact details**  
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Rotterdam  
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## Additional identifiers

**Protocol serial number**  
196429 / 2000 / 222

## Study information

**Scientific Title**  
Pathophysiological aspects of hyperglycemia in children with meningococcal sepsis and septic shock: a prospective, observational cohort study

**Study objectives**

The objective of the present study was to investigate the occurrence of hyperglycemia in relation with the insulin response and exogenous factors, such as glucose intake and drug use, in a homogenous group of critically ill children with meningococcal sepsis and/or meningococcal septic shock.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Medical Ethics Committee (MEC) approved in March 2000 (ref: 196429 / 2000 / 222)

**Primary study design**

Observational

**Study design**

Prospective observational cohort study

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Meningococcal sepsis

**Interventions**

Observational cohort study. Blood samples to be taken on admission, and at 24 and 48 hours thereafter.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. Blood glucose levels
  2. Plasma levels of
    - 2.1. insulin
    - 2.2. C-peptide
    - 2.3. cortisol
    - 2.4. cytokines
    - 2.5. C-reactive protein (CRP)
    - 2.6. cytokines
- Measured on admission, and at 24 and 48 hours.

**Key secondary outcome(s)**

None

**Completion date**

01/05/2004

# Eligibility

## Key inclusion criteria

The study population consisted of previously healthy children admitted to the Pediatric Intensive Care Unit (PICU) of the Erasmus Medical Centre - Sophia Childrens Hospital between October 1997 and May 2004, suffering from meningococcal sepsis, i.e. sepsis with petechiae /purpura

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Child

## Sex

All

## Key exclusion criteria

1. Pre-existing endocrine or chromosomal abnormalities
2. Radiation or chemotherapy within the previous 6 months

## Date of first enrolment

01/10/1997

## Date of final enrolment

01/05/2004

# Locations

## Countries of recruitment

Netherlands

## Study participating centre

Dr Molewaterplein 60

Rotterdam

Netherlands

3000CB

# Sponsor information

## Organisation

Erasmus Medical Centre, Sophia Childrens Hospital (Netherlands)

**ROR**

<https://ror.org/047afsm11>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Erasmus Medical Centre, Sophia Childrens Hospital (Netherlands)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration