

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

Submission date 22/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/07/2010	Condition category 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Prospective observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a patient information sheet

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 measure

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.

Secondary outcome measures

None

Overall study start date

01/10/1997

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

Age group

Child

Sex

Both

Target number of participants

80

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)

Sponsor details

Dr Molewaterplein 60

Rotterdam

Netherlands

3000CB

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre, Sophia Childrens Hospital (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration