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

Submission date	Recruitment status	[_] Prospectively registered
22/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/07/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/07/2010	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Koen Joosten

Contact details
Dr Molewaterplein 60
Rotterdam
Netherlands
3000CB

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