Presepsin in young infants with fever

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Plasma presepsin level can differentiate between bacterial and viral infections in young infants with fever of unknown origin

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20439

Source
Nationaal Trial Register

Brief title
PRESEPSIN

Health condition

Fever of unknown origin

Sponsors and support

Primary sponsor: Investigator initiated
Source(s) of monetary or material Support: Noordwest Academie

Intervention

Outcome measures

Primary outcome

Plasma presepsin level in different patient groups at the timepoint presentation at emergency department

Secondary outcome

a cut-off value of plasma presepsin level for bacterial infection, the diagnostic accuracy of presepsin in detection of bacterial infection, a clinical pattern associated with probable bacterial infection based on high and low presepsin levels. All secondary outcomes will be measured at the timepoints presentation at emergency department.

Study description

Background summary

Rationale: Rapid and accurate biomarkers for the detection of bacterial infections are warranted in young infants presenting at the emergency department. Delay in diagnosis may lead to significant morbidity and even mortality. Current diagnostic strategies for the detection of bacterial infections are either time-consuming (at least 12 hours for e.g. blood cultures and infection markers) or suboptimal in its accuracy (infection markers have a sensitivity around 80%). Presepsin proved to be an accurate biomarker for the detection of sepsis in adults and neonates and is therefore promising in the subgroup of infants under 3 months presenting with fever of unknown origin. Objective: To compare differences in plasma presepsin levels between young infants with a bacterial and a viral infection. Secondary objectives are to determine a cut-off value for bacterial infection; to assess the diagnostic accuracy of presepsin in the detection of bacterial infections in young infants presenting with fever of unknown origin, also as compared to currently used infection parameters; to divide young infants in which no pathogen is found into a group with high and low prespsin levels and compare differences in clinical characteristics between these two groups, in order to identify a clinical pattern associated with probable bacterial infection. Study design: Prospective observational cohort study Study population: Young infants (<3 months of age) presenting at the emergency department with fever of unknown origin and undergoing routine blood sampling will be eligible for study participation. For this study, 230 patients will be included. Main study parameters/endpoints: see objectives, in short: the plasma presepsin level, a cut-off value of plasma presepsin level for bacterial infection, the diagnostic accuracy of presepsin in detection of bacterial infection, a clinical pattern associated with probable bacterial infection based on high and low presepsin levels.

Study objective

Plasma presepsin level can differentiate between bacterial and viral infections in young infants with fever of unknown origin

Study design

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Contacts

Public
Noordwest Ziekenhuisgroep - locatie Alkmaar
Charlotte Nusman

5653
Scientific
Noordwest Ziekenhuisgroep - locatie Alkmaar
Charlotte Nusman

5653

Eligibility criteria

Inclusion criteria

- Age under 3 months - Temperature >38,0 □C (measured by parents or at emergency department, tympanic or rectally) - Fever of unknown origin - Visiting emergency department from home - Submitted to blood sampling for infection as part of routine care, i.e. blood culture and/or infection parameters - Informed consent of parent(s) or legal guardian(s)

Exclusion criteria

None

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	230
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-02-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54911
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9293
CCMO	NL74009.029.20
OMON	NL-OMON54911

Study results