Presepsin in young infants with fever

Gepubliceerd: 21-02-2021 Laatst bijgewerkt: 13-01-2025

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20439

Bron
Nationaal Trial Register

Verkorte titel
PRESEPSIN

Aandoening

Fever of unknown origin

Ondersteuning

Primaire sponsor: Investigator initiated
Overige ondersteuning: Noordwest Academie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

1

Contactpersonen

Publiek

Noordwest Ziekenhuisgroep - locatie Alkmaar
Charlotte Nusman

5653

Wetenschappelijk

Noordwest Ziekenhuisgroep - locatie Alkmaar
Charlotte Nusman

5653

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	230
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-02-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54911
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten