Screening for complement donors with no or low antibodies to Neisseria meningitidis

Published: 15-01-2014
Last updated: 23-04-2024

To identify complement donors with no or low antibodies to Meningococcal strains to be used used as a complement source in SBAs against a panel of meningococci during evaluation of clinical trial samples

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON38256

Source
ToetsingOnline

Brief title
Identification of seronegative complement donors

Condition

- Bacterial infectious disorders

Synonym
infection., Meningococci

Research involving
Human

Sponsors and support

Primary sponsor: Crucell Holland B.V.
Source(s) of monetary or material Support: Crucell Holland B.V.

Intervention

Keyword: active complement, antibodies, Meningitis, meningococci

Outcome measures

Primary outcome

N.A.

Secondary outcome

N.A.

Study description

Background summary

Due to the severity of the disease, challenge studies are unethical. Therefore, existing meningococcal vaccines have been licensed using the results of an in vitro surrogate of protection: the Serum Bactericidal Assay (SBA) .
In this study, suitable complement donors will be identified whose serum can be used as a complement source in SBAs against a panel of meningococci during evaluation of clinical trial samples

Study objective

To identify complement donors with no or low antibodies to Meningococcal strains to be used used as a complement source in SBAs against a panel of meningococci during evaluation of clinical trial samples

Study design

Observational study in healthy volunteers.

Study burden and risks

Risk regarding blood drawing: risk to bruise or infection

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy males and females

Exclusion criteria

Currently taking antibiotics or have taken antibiotics in the 2 weeks preceding blood collection.
Having had any vaccination in the 2 weeks preceding blood collection.
Blood donation outside the limits of Sanquin

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2014
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	15-01-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL46901.058.13