GBS carriage in pregnant women - Part 2 of the Netherlands Observational study on Gbs disease, Bacterial virulence and protective Serology - (NO GBS)

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In this observational cohort study we will determine the prevalence and genetic profile of colonizing GBS isolates in pregnant women in the Netherlands. We will collect serum from pregnant women and their newborns to determine specific IgG...

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

Summary

ID

NL-OMON52426

Source
ToetsingOnline

Brief title
GBS carriage in Dutch pregnant women

Condition

- Bacterial infectious disorders
- Central nervous system infections and inflammations
- Neonatal and perinatal conditions

Synonym
Streptococcus agalactiae or group B Streptococcus or GBS. Colonization of Carriage. Sepsis/severe bacterial bloodinfection. Bacterial infection of the membranes lining in the brain or meningitis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: GBS carriage, Pregnant woman

Outcome measures

Primary outcome

- Prevalence of GBS carriage in pregnant women in the Netherlands

- Whole genome sequencing of colonizing GBS isolates with Illumina HiSeq at the Wellcome Trust Sanger Institute

- Specific IgG concentrations by enzyme-linked immunosorbent assay (ELISA) and functionality against GBS vaccine targets in maternal serum from pregnant women colonized with GBS and non-carriers, and cord blood from their newborns

Secondary outcome

- Comparison of specific IgG distributions and functionality against vaccine targets at delivery in pregnant women colonized with GBS and mothers of patients with invasive GBS disease

- Comparison of specific IgG distributions and functionality against vaccine targets in newborns from pregnant women colonized with GBS (blood spots and cord blood) and patients with invasive GBS disease (blood spots and serum)

- Genome wide association study comparing invasive to colonizing GBS isolates

Study description

Background summary

Streptococcus agalactiae (Group B Streptococcus, GBS) and E. coli are the leading cause of neonatal sepsis and meningitis. One in five pregnant women carries GBS asymptomatically. Transmission of GBS bacteria to the neonate can result in invasive disease, with a case fatality rate of 7%.
Dutch GBS prevention guidelines recommend intrapartum antibiotic prophylaxis for pregnant women with risk factors for GBS disease. We have previously shown that the incidence of neonatal GBS disease is increasing, despite guideline implementation in 1999. In addition, current guidelines recommend bacterial prophylaxis and treatment for mothers and their children based on a risk-calculation. With this strategy a bigger group of children is exposed to antibiotics than are most likely infected by GBS or E. coli. Another short-coming in the current guidelines is the focus on early onset disease. The incidence of late onset disease, i.e. after 7 days of age, has not changed in the western world in the past decades.
Improved risk assessment, a better understanding of GBS pathophysiology and new prevention strategies are needed to counter this increase and decrease the exposure to antibiotics early in life.
Vaccination against GBS during pregnancy might reduce invasive disease in neonates. GBS vaccines were shown to be safe and immunogenic in pregnant woman. However, the further evaluation of these vaccines is hampered because of the high costs of a phase 3 RCT with clinical endpoints. Immune correlates of protection are needed to evaluate potential effectiveness of these GBS vaccines.

Study objective

In this observational cohort study we will determine the prevalence and genetic profile of colonizing GBS isolates in pregnant women in the Netherlands. We will collect serum from pregnant women and their newborns to determine specific IgG concentrations and functionality against vaccine targets that protect against GBS colonization.

The primary objectives of the NO GBS study part 2 are to determine the prevalence and genetic profile of colonizing GBS bacteria, and to determine IgG antibody concentrations and functionality against GBS vaccine targets in Dutch pregnant woman that are associated with protection against GBS colonization.

The secondary objectives are to determine genetic determinants of GBS for invasive disease, and to determine immunological parameters associated with protection against invasive GBS disease. Results from other parts of the NO GBS study will be added to study these secondary objectives.

Study design

We will conduct a prospective, observational, multi-centre cohort study on GBS carriage in Dutch pregnant women. We will collect the medical correspondence about the obstetric history and outcome of the current pregnancy, GBS isolates, and serum from mothers and their newborns.

Study burden and risks

Patients will be treated according to national and local guidelines. Blood and recto-vaginal swabs will be collected .The burden is minor and risks are minimal.

Blood from the newborn will be collected from the umbilical cord from the placenta after the cord is cut at delivery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Pregnant women who plan to deliver in participating hosptal.

Exclusion criteria

Oral or intravenous antibiotic treatment in the month prior to the first GBS colonization culture
In case the newborn develops culture positive invasive GBS disease in the first 90 days of life, the results will be excluded from the analysis of the carriage study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2019
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	28-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-05-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL63124.018.17