

# Implementation of a cost effective strategy to prevent neonatal infection by group B-hemolytic streptococcus

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To find the most cost effective GBS prevention strategy to reduce neonatal morbidity and mortality by GBS for the Netherlands.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bacterial infectious disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON37307

### Source

ToetsingOnline

### Brief title

GBS implementation study

### Condition

- Bacterial infectious disorders
- Neonatal and perinatal conditions

### Synonym

early onset group B streptococcus disease

### Research involving

Human

### Sponsors and support

**Primary sponsor:** TNO

**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Group B Streptococcus, Implementation, Neonatal infection, Prevention

## Outcome measures

### Primary outcome

Percentage adherence to the different prevention strategies compared with the percentage adherence to the current Dutch guideline.

### Secondary outcome

Adherence of the prevention strategies, clinical and process outcomes, cost effectiveness analysis of the different prevention strategies, experiences of pregnant women and care providers.

## Study description

### Background summary

Current prevention in the Netherlands of early onset group B- hemolytic streptococcus infection (EOGBS) within the first week of life can be improved. Perinatal mortality among children with EOGBS is 9.2%.

Intrapartum Antibiotic Prophylaxis (IAP) is effective in prevention of vertical transmission of GBS from mother to child. It is not clear which pregnant women need treatment with IAP.

Different prevention strategies are available, based on either screening during pregnancy on GBS carriage with the mother (screening strategy), risk factors during labour associated with EOGBS (risk factor strategy) or a combination of screening and risk factors (combination strategy).

A theoretical model study of TNO showed the combination strategy to be most cost-effective strategy in the Netherlands. The risk factor strategy was cost effective too. The screening strategy, as in use in the USA, has the highest effect in reduction of morbidity and mortality at highest costs.

The current Dutch guideline seemed not very cost effective. The model study was based on 100% adherence of the strategy. The question remains what cost effectiveness of the different strategies is in daily practice.

In this study three strategies will be implemented in three regions and compared on real-time cost effectiveness.

## Study objective

To find the most cost effective GBS prevention strategy to reduce neonatal morbidity and mortality by GBS for the Netherlands.

## Study design

Implementation study.

Intervention: Implementation of three different GBS prevention strategies in three regions in the Netherlands.

## Study burden and risks

Pregnant women will be included from the 30 th week of pregnancy onward. In the combination strategy a culture will be taken between 35 and 37 weeks of pregnancy to detect GBS carriage. The culture will be taken during a regular pregnancy consult. There is no need for the pregnant women for a extra visit. During the next consult the test result will be discussed with the pregnant woman. There are no risks related to taking the culture.

Intrapartum antibiotic prophylaxis will be provided to GBS carriers with a risk factor in the combination strategy and to all pregnant women with a risk factor in the riskfactor strategy.

Antibiotic prophylaxis given intravenous, demands hospital admittance during labour. In the third strategy, the revised Dutch guideline, no extra actions are performed.

Pregnant women are asked to fill a form on decisional conflict during pregnancy. After delivery mothers are asked to fill a form on satisfaction.

## Contacts

### Public

TNO

Wassenaarseweg 56

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Midwives, gynecologists and pediatricians working in one hospital and the region around this hospital. All pregnant women in care of the midwife or gynecologist in the hospital region from pregnancy week 30 onwards.

### Exclusion criteria

Pregnant women who refuse the 'new' policy of GBS prevention are offered the care as usual.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

### Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2013
Enrollment:	1260
Type:	Actual

## Ethics review

Approved WMO	
Date:	12-12-2012
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	NL41673.058.12