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Bordetella pertussis serology in pregnancy

Submission date	Recruitment status	[_] Prospectively registered
27/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/01/2021	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC/02/14 P02.205; NTR448

Study information

Scientific Title

Bordetella pertussis serology in pregnancy

Acronym
Kinkzwang

Study objectives
About 6% of the population between three and 79 years suffers each year of a B. pertussis infection, including pregnant women. These women are a source of infection for their newborn babies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local medical ethics committee (Commissie Medische Ethiek, Leids Universitair Medisch Centrum, Leiden) (ref: P02-205).

Study design
Observational, single centre, cross-sectional survey

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
B. pertussis infection in pregnancy

Interventions
Serology for Immunoglobulin G (IgG) against pertussis toxin in blood of the mother and cord blood. The test used is the test as used by the National Institute for Public Health and the Environment (RIVM) (The Netherlands).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Positive B. pertussis serology
2. Cata questionnaires

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/2002

Completion date
01/06/2006

Eligibility

Key inclusion criteria
All pregnant women delivering at the department of gynecology and obstetrics of the Groene Hart Hospital.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
500

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/08/2002

Date of final enrolment
01/06/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Groene Hart Hospital
Gouda

Netherlands
2800 BB

Sponsor information

Organisation
Groene Hart Hospital (The Netherlands)

Sponsor details
Department of Gynaecology and Obstetrics
P.O. Box 1098
Gouda
Netherlands
2800 BB

Sponsor type
Hospital/treatment centre

Website
http://www.ghz.nl/

ROR
https://ror.org/0582y1e41

Funder(s)

Funder type
Government

Funder Name
National Institute for Public Health and the Environment (RIVM) (The Netherlands) - performing the serology

Funder Name
All other costs are covered by the principal investigator.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2009	05/01/2021	Yes	No