Pertussis in Pregnancy Safety (PIPS) Study

First published: 19/12/2013

Last updated: 10/03/2014

Study Ongoing

Administrative details

EU PAS number

EUPAS5418

Study ID

6031

DARWIN EU® study

No

Study countries

☐ New Zealand

Study description

This is a three-component observational study that will collect data both retrospectively and prospectively. Data for all pregnant women and their infants in NZ between 2009 and 2013 will be obtained and pertussis vaccine exposure during pregnancy verified (Study One). Two sub-studies will actively follow

mothers who received Tdap during pregnancy with one also following their infants for one year after birth (Study Two and Three). Study One will involve de-identified data linkage for all pregnant women and their infants for the period 2009–2013 and the intensive monitoring studies (i.e., Study Two and Three) will prospectively follow up the mother for one month after vaccination (Study Two) with a further group being followed for both maternal and infant outcomes for one year from the birth of the infant (Study Three).

Study status

Ongoing

Research institutions and networks

Institutions

University of Auckland

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Institution

Immunisation Advisory Centre

University of Otago Christchurch, New Zealand

Contact details

Study institution contact

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Primary lead investigator

Helen Petousis-Harris

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/12/2013

Study start date

Planned: 03/02/2014

Actual: 16/01/2014

Date of final study report

Planned: 30/01/2015

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

GlaxoSmithKline, Canterbury District Health Board

Study protocol

Protocol_final draft_301013_reduced.pdf (1.87 MB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To evaluate health outcomes for pregnant women and their infants following administration of Tdap (pertussis-containing vaccine) during pregnancy.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07AJ52) pertussis, purified antigen, combinations with toxoids

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Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

325000

Study design details

Outcomes

Adverse Events following administration of pertussis vaccine (Tdap) during pregnancy, The difference in hospital-related outcomes of those vaccinated or not with Tdap during pregnancy in all NZ women pregnant between 2009 & 2013.The difference in birth outcomes and hospital-related outcomes of infants born to mothers vaccinated or not with Tdap during pregnancy in all NZ women pregnant between 2009 & 2013.

Data analysis plan

Logistic regression will estimate odds ratios for the risk for (specific) adverse events for mothers and infants in vaccine exposed and unexposed groups. Age, ethnicity and socioeconomic deprivation and season for hospital admission will be included as additional explanatory variables. Each person will only be counted once for each hospitalisation, the primary diagnosis and repeat admissions for the same episode will be removed, including transfers from one hospital to another.For diagnosis where individuals may have multiple admissions for different occurrences and the outcome is a count, Poisson regression will be used with testing and adjustment for overdispersion where required.The temporal relationship between onset of events and vaccination will be presented including distribution where appropriate.Serious adverse events will be reported as detailed clinical cases.To analyse the effect of Tdap on still births we will perform a survival analysis.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Conflicts of interest of investigators

Conflict of Interest Survey HelePH.pdf (59.84 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Exposure registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No