200405 - An observational retrospective database analysis to estimate the risk of Multiple Sclerosis (MS) following vaccination with Arepanrix™ in Manitoba, Canada

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Study Finalised

Administrative details

EU PAS number

EUPAS6817

Study ID

31668

DARWIN EU® study

No

Study countries

Canada

Study description

The purpose of this database study is to assess if Arepanrix™ vaccination during the 2009 H1N1 influenza pandemic was associated with an increased risk of multiple sclerosis in Manitoba, Canada.This observational, retrospective, propensity-score matched cohort study using the Manitoba Immunization Monitoring System (MIMS) and the hospital, physician, and prescription claims databases of the Manitoba Health (MH) Database System will assess if Arepanrix™ vaccination during the 2009 H1N1 influenza pandemic was associated with an increased risk of multiple sclerosis (MS) and other demyelinating conditions not ultimately leading to a multiple sclerosis diagnosis in Manitoba, Canada.The vaccinated cohort will comprise adults and children greater than 6 months of age (at the time of vaccination) who normally reside in Manitoba with a MIMS record for pandemic H1N1 influenza vaccination between September 15, 2009 and March, 15, 2010. Individuals with MIMS records for Trivalent Inactivated seasonal influenza Vaccine (TIV) during this period will account for potential confounding or effect modification by seasonal influenza vaccination. Individuals with no records of H1N1 or seasonal influenza vaccination will constitute the unvaccinated cohort. Matching will be performed using propensity scores. An MS case will be defined by ≥3 hospital, physician or prescription claims for MS using the International Classification of Diseases (ICD9/10) codes to define a case of MS. The date of diagnosis of MS will be considered the date of the first medical contact for any of the MS diagnostic codes.

Study status

Finalised

Research institutions and networks

Institutions

Community Health Sciences, University of Manitoba

Contact details

Study institution contact

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Study contact

Vx.publicdisclosureglobal@gsk.com

Primary lead investigator

Salah Mahmud

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/08/2014

Study start date

Actual: 30/09/2014

Date of final study report

Actual: 07/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline Biologicals

Study protocol

200405-protocol-redact.pdf (344.83 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To assess whether administration of Arepanrix™ was associated with an increased risk of incident MS.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

AREPANRIX

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

Adults and children above 6 months of age (at the time of vaccination) who normally resided in Manitoba and had been registered with MH for at least 1 year before the enrolment period. The entire population of Manitoba was considered for inclusion.

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

1

Study design details

Outcomes

Occurrence of MS during the period of one year following administration of Arepanrix™ among an exposed cohort and during an equivalent time period in the unexposed cohort (15 September 2009 to 15 March 2010). Occurrence of MS from administration of Arepanrix™ until 31 December 2012 and occurrence of demyelinating events which do not ultimately lead to a diagnosis of MS (i.e. never have a diagnostic claim for MS) during one year following administration

of Arepanrix™ and until 31 December 2012, respectively, among an exposed cohort and during equivalent time periods in the unexposed cohort.

Data analysis plan

The study is a retrospective analysis of population-based cohorts of subjects, whose vaccination status and health events before and after vaccination are recorded in various MH administrative databases. A propensity-score (PS) matched cohort analysis will be conducted using de-identified records obtained by linking the electronic database of the Manitoba Immunization Monitoring System (MIMS) with the hospital, physician and prescription claims databases of MH.PS methods are one approach to constructing more comparable groups with respect the distribution of important disease (or outcome) predictors (confounders) to reduce biases due to lack of random treatment assignment in observational studies. Each vaccinated individual will be matched to an individual who did not receive any influenza vaccines during the study period.Cox proportional hazard models, with stratification on the PS matched pairs, will be used to estimate relative risks (hazards ratios) associated with vaccination.

Documents

Study results

gsk-200405-clinical-study-report-redact.pdf (1.4 MB)

gsk-200405-clinical-study-report-redact_2.pdf (2.13 MB)

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.

Data sources

Data source(s), other

Manitoba Health Population Registry (MHPR) Canada, Manitoba Immunization Monitoring System (MIMS) Canada, Manitoba Health (MH) administrative databases Canada, Drug Program Information Network (DPIN) Canada, Hospital Abstracts database and the Medical Services database Canada

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Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Drug registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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

Unknown