Systematic Review and meta-analysis of PASS Studies Assessing the Effectiveness of Risk Minimisation Measures

First published: 20/03/2018

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS23245

Study ID

23435

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Spain
- ☐ United Kingdom

Study description

Risk minimisation measures are designed to mitigate potentially manageable risks of medicines. The effectiveness of these measures is uncertain. This cumulative systematic review and meta-analysis of PASS studies conducted to evaluate the effectiveness of risk minimisation studies provides data upon which to assess the future role of these studies.

Study status

Ongoing

Research institutions and networks

Institutions

OXON Epidemiology

☐ Spain

☐ United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **ENCePP partner**

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Bayer Epidemiology Berlin

Contact details

Study institution contact

Esther Artime esther.artime@oxonepi.com

Study contact

esther.artime@oxonepi.com

Primary lead investigator

Nawab Qizilbash MBChB MRCP(UK) BSc MSc DPhil(Oxon.)

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/03/2016

Study start date

Actual: 28/03/2016

Date of final study report

Planned: 25/05/2018

Sources of funding

- Other

More details on funding

OXON Epidemiology

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Scoping review (including literature review)

Main study objective:

To describe study characteristics, results, and regulatory consequences, in EU PASS RM Survey Study reports registered in the EU PAS Register.To quantify and pool (where appropriate) data on participation rates, receipt, knowledge, behaviour, use and reading in EU RM Survey Study reports registered in the EU PAS Register.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

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

0

Study design details

Outcomes

Study characteristics, participation rates, receipt, knowledge, behaviour, use and reading, and regulatory consequences

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Data analysis plan

Analyses are mainly descriptive, with numbers. proportions and Forest plots and other graphs. Where feasible, aggregate study-level data will be pooled overall and by aRMM type using random and fixed effects models.

Documents

Study publications

Vora P, Artime E, Soriano-Gabarro M, Qizilbash N, Asiimwe A. A Review of Studie...

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 sources (types)

Other

Data sources (types), other

EU PAS Register, EMA, Pharmaceutical companies, MedLINE

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