

Risk factors of intussusception in children under the age of 1 year: retrospective case-control study

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Study

Planned

Administrative details

EU PAS number

EUPAS9814

Study ID

9815

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Retrospective multicentre matched case-control study on the risk factors of intussusception in children under the age of 1 year

Study status

Planned

Research institutions and networks

Institutions

Paul-Ehrlich-Institut

☐ Germany

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Institution

EU Institution/Body/Agency

Regulatory Authority

Contact details

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Study contact

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Primary lead investigator

Brigitte Keller-Stanislowski

Study timelines

Date when funding contract was signed

Planned: 27/02/2015

Actual: 09/03/2015

Study start date

Planned: 01/05/2015

Date of final study report

Planned: 30/04/2018

Sources of funding

- Other

More details on funding

Paul-Ehrlich-Institut

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

Disease epidemiology

Other

If 'other', further details on the scope of the study

Further research on the risk factors of intussusception

Main study objective:

This study aims at further elucidating the the causes of intussusception in the first year of life with a special focus on infections and vaccinations preceding intussusception.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medical condition to be studied

Intussusception

Population studied

Age groups

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

Estimated number of subjects

240

Study design details

Data analysis plan

Logistic regression analysis

Data management

Data sources

Data sources (types)

[Other](#)

Data sources (types), other

Retrospective case- and control-based data collection

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