SSRIs during pregnancy and risk of autism spectrum disorder and attention deficit hyperactivity disorder: systematic review of observational studies

First published: 03/05/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18909

Study ID

23798

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Perform a systematic review of observational studies assessing the risk of autism spectrum disorder and attention deficit hyperactivity disorder associated with maternal selective serotonin re-uptake inhibitor (SSRI) exposure during pregnancy.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Morales Daniel Daniel.Morales@ema.europa.eu

Study contact

Daniel.Morales@ema.europa.eu

Primary lead investigator

Morales Daniel

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 04/07/2016

Actual: 04/07/2016

Study start date
Planned: 18/07/2016

Actual: 18/07/2016

Data analysis start date
Planned: 25/07/2016

Actual: 01/08/2016

Date of final study report
Planned: 19/06/2017

Actual: 15/01/2018

Sources of funding

- EMA

Study protocol

EUPAS18909.protocol.pdf (63.19 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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 undertake a systematic review identifying observational studies evaluating risk of autism spectrum disorder and attention deficit hyperactivity disorder

following maternal exposure to selective serotonin re-uptake inhibitors during pregnancy. To assess confounding adjustment within studies and the different effect estimates for different reference groups reported.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06AB) Selective serotonin reuptake inhibitors

Selective serotonin reuptake inhibitors

Medical condition to be studied

Autism spectrum disorder

Attention deficit hyperactivity disorder

Population studied

Short description of the study population

Women during pre-pregnancy or pregnancy with or without serotonin re-uptake inhibitor (SSRI) exposure.

Age groups

- Infants and toddlers (28 days – 23 months)

- Children (2 to < 12 years)

Estimated number of subjects

10000

Study design details

Outcomes

ASD and ADHD

Data analysis plan

To describe the type of studies, their characteristics and the variables used for confounding adjustment by them. To describe the types of comparator groups used to compare risk from SSRI exposure with a focus on:maternal exposure during pregnancy compared to all unexposed women, maternal exposure during the pre-pregancy period compared to all unexposed women, maternal exposure during pregnancy compared to all unexposed women with an affective disorder, paternal exposure during pregnancy, and sibling designs. To explore the effect of meta-analysis for different exposures using generic inverse variance method of analysis in Review Manager.

Documents

Study results

EUPAS18909.summary.results.pdf (122.67 KB)

Study publications

Morales DR, Slattery J, Evans S, Kurz X. Antidepressant use during pregnancy an...

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)

Published literature

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