Infant and childhood neurodevelopmental outcomes following prenatal exposure to selective serotonin reuptake inhibitors: overview and design of a Finnish Register-Based Study (FinESSI)

First published: 18/08/2015

Last updated: 18/08/2015

Study Ongoing

Administrative details

EU PAS number

EUPAS10694

Study ID

10695

DARWIN EU® study

No

Study countries

Finland

Study description

This is a cohort study of national registers in Finland: the Medical Birth Register, the Hospital Discharge Register including inpatient and outpatient data, the Drug Reimbursement Register, and the Population Register. The total study population includes 845,345 women and their live-born, singleton offspring aged 14 or younger and born during Jan 1st 1996-Dec 31st 2010. We compare the prevalence of psychiatric and neurodevelopmental outcomes in offspring exposed prenatally to SSRIs to offspring exposed to prenatal depression and unexposed to SSRIs. Associations between exposure and outcome are assessed by statistical methods including specific modeling to account for correlated outcomes within families and differences in duration of follow-up between the exposure groups. The study has the potential for significant public health importance in providing information on prenatal exposure to SSRIs and long-term neurodevelopment.

Study status

Ongoing

Research institutions and networks

Institutions

University of Turku

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Department Child Psychiatry

Turku University, Child psychitary Turku, Finland, Columbia University NY, U.S.

Contact details

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Primary lead investigator

Andre Sourander

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/08/2010

Study start date

Actual: 15/09/2010

Data analysis start date
Actual: 03/01/2011

Date of final study report
Planned: 31/12/2015

Sources of funding

- Other

More details on funding

NIMH

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:

The objective of the FinESSI study is to investigate if prenatal SSRI exposure increases the risk of adverse psychiatric or neurodevelopmental outcome until age 14, controlling for maternal depression.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06AB) Selective serotonin reuptake inhibitors

Selective serotonin reuptake inhibitors

Medical condition to be studied

Neurodevelopmental disorder

Population studied

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)

- Adolescents (12 to < 18 years)

Special population of interest

Pregnant women

Estimated number of subjects

64.000

Study design details

Outcomes

The specific outcomes under study include: offspring depression, anxiety, autism spectrum disorders (ASD), and attention-deficit hyperkinetic disorders (ADHD).

Data analysis plan

Clinically relevant and plausible covariates were first tested and included in the models if associated with both exposure and outcome at P<0.1. To take into account the fact that children born from 1996-2010 were aged 0-14 years at the end of the follow-up in 2010, we use survival methods. Events in the survival analysis were defined as age at the first diagnosis of the studied outcome. Separate survival analyses were conducted for each of the four outcomes. We plotted the cumulative incidence of offspring diagnoses among the SSRI exposed, the Psychiatric disorder, no medication group, the SSRI discontinued group and the Unexposed group. To compare offspring psychiatric diagnoses between these four groups, Cox proportional hazards models were used. Each outcome was analyzed separately by fitting two models: a crude model adjusted only for sex, and a model adjusted for additional covariates associated with the exposure and each specific outcome.

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

Drugs and Pregnancy Finland, Hospital discharge register Finland

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-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