

# Maternal Exposure to Antidepressants and Psychiatric Outcomes Among Offspring in a National Birth Cohort (Prenatal SSRIs and offspring Psychiatric Outcome)

**First published:** 12/05/2020

**Last updated:** 12/05/2020

Study

Planned

## Administrative details

### EU PAS number

EUPAS33119

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### Study ID

33120

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### DARWIN EU® study

No

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### Study countries

 Finland

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### Study description

The overall objective of this project is to address novel research questions using comprehensive registry data in a large, national Finnish birth cohort on the relationship between use of selective serotonin reuptake inhibitor (SSRI) medications during pregnancy and psychiatric disorders from birth to age 21. The safety of SSRIs during pregnancy is a question of clear importance to patients and clinicians. The prevalence of major depression in pregnancy is 5-10%, and as many as 20% of pregnant women experience depressive symptoms. Gestational SSRI use has also been increasing in other countries, including Finland, where the proportion of pregnant women purchasing antidepressants increased significantly from 1996 to 2010. Given the particularly high prevalence of depression in women and the increasing use of SSRIs, more research is needed to investigate potential short- and long-term harms to the fetus. Only recently have studies attempted to investigate this issue in population-based birth cohorts. We have previously investigated relationships between maternal SSRIs and several neuropsychiatric outcomes, including depression, anxiety, autism spectrum disorder, attention deficit hyperactivity disorder, and speech/language disorders until 14 years' age. We shall extend the follow up until age 21, which will permit us to examine the risk trajectory of the previously observed increased risk of depression following maternal SSRI exposure and will markedly increase the sample size. The additional 7 years of follow-up, through adolescence and early adulthood, will permit us to examine whether the sharp rise in risk of the previously observed offspring depression continues into these age groups. This will also allow us to augment the sample of maternal SSRI-exposed subjects, for a total of estimated ~29,000 children born from 1996-2016.

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### **Study status**

Planned

## Research institutions and networks

## Institutions

University of Turku

**First published:** 01/02/2024

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Institution

Columbia University, NY New York

## Contact details

### Study institution contact

Heli Malm [heli.malm@hus.fi](mailto:heli.malm@hus.fi)

Study contact

[heli.malm@hus.fi](mailto:heli.malm@hus.fi)

### Primary lead investigator

Heli Malm

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 31/10/2018

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**Study start date**

Planned: 01/06/2020

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**Data analysis start date**

Planned: 30/09/2020

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**Date of interim report, if expected**

Planned: 31/03/2021

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**Date of final study report**

Planned: 31/10/2022

## Sources of funding

- Other

## More details on funding

National Institute of Mental Health, U.S.

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To investigate the impact of antenatal SSRI exposure on offspring psychiatric disorders into early adulthood in a national birth cohort

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

(N06AB) Selective serotonin reuptake inhibitors

Selective serotonin reuptake inhibitors

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**Medical condition to be studied**

Childhood depression

Pregnancy

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**Additional medical condition(s)**

Antenatal depression, Offspring diagnoses of depression, anxiety, ADHD and autism spectrum disorders

## 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)
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### Special population of interest

Pregnant women

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### Estimated number of subjects

242000

## Study design details

### Outcomes

Offspring diagnosis of depression. Offspring diagnoses of Anxiety disorders  
Autism spectrum disorder (ASD) Attention deficit hyperactivity disorder (ADHD)  
Tourette syndrome (TS) Speech, motor, and scholastic disorders

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### Data analysis plan

To determine whether the sharp rise in risk of depression observed in our previous research (defined as register diagnoses of major depressive disorder/other depressive disorders) among maternal SSRI-exposed subjects at 12-14 years of age continues into older age groups, we will first visually examine plots of cumulative incidence functions with confidence bands (based on Kaplan-Meier estimators), then we will fit Cox regression models. We will then add interaction terms for the product of maternal exposure category and age (or a more general function of age, for example, a dichotomous indicator of onset age, treated as a time-dependent covariate) to Cox models. Significant ( $p < 0.05$ ) p-values for these product terms will suggest that the risk of depression associated with prenatal SSRI exposure varies by offspring age. We will estimate separate HRs for the association of maternal SSRI exposure with depression diagnosed before and after the median age of diagnosis.

## 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)**

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No