Anti-thyroid Drug Use during pregnancy and risk of congenital anomalies: systematic review of observational studies and methodological considerations (Anti-thyroid drugs in pregnancy)

First published: 15/08/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS30990

Study ID

30991

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study will undertake a systematic review of the literature to identify observational studies examining maternal exposure to methimazole, carbimazole or propylthiouracil during pregnancy and the risk of congenital anomolies. Effect estimates from these studies will then be meta-analysed according to their comparator groups defined.

Study status

Ongoing

Research institutions and networks

Institutions

University of Dundee

United Kingdom

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Institution | Educational Institution

Contact details

Study institution contact

Daniel Morales d.r.z.morales@dundee.ac.uk

Study contact

d.r.z.morales@dundee.ac.uk

Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/06/2019

Actual: 03/06/2019

Study start date

Planned: 10/06/2019

Actual: 10/06/2019

Date of final study report

Planned: 01/10/2019

Sources of funding

- Other

More details on funding

University of Dundee internal resources

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

Main study objective:

To measure the association between maternal exposure to methimazole, carbimazole and propylthiouracil and the risk of congenital anomalies in offspring from existing observational studies.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H03BA02) propylthiouracil

propylthiouracil

(H03BB01) carbimazole

carbimazole

(H03BB02) thiamazole

thiamazole

Medical condition to be studied

Hyperthyroidism

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

1000000

Study design details

Outcomes

Congenital anomalies in offspring

Data analysis plan

The study characteristics and heterogeneity in confounding adjustment will first be described. Crude and adjusted effect estimates will be calculated on the natural log scale and pooled using the generic inverse variance method of analysis. Random-effects models will be generated analysis for each type of exposure and comparator group separately. A leave-one-out analysis will be undertaken to test the robustness of the results. Analyses will be conducted in Review Manager 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). Publication bias will be assessed by testing for funnel-plot asymmetry and using the Egger test as appropriate.

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

No