

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

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS30990

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### Study ID

30991

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### DARWIN EU® study

No

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### Study countries

☐ United Kingdom

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## 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 anomalies. Effect estimates from these studies will then be meta-analysed according to their comparator groups defined.

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## 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

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Study contact

[d.r.z.morales@dundee.ac.uk](mailto: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

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### Study start date

Planned: 10/06/2019

Actual: 10/06/2019

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### 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

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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 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

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**Medical condition to be studied**

Hyperthyroidism

## Population studied

**Age groups**

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**

1000000

## Study design details

**Outcomes**

Congenital anomalies in offspring

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## **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**

### **Data sources**

#### **Data sources (types)**

[Published literature](#)

### **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