Assesing the Safety of Antihypertensive medication in Pregnancy (ASAP)

First published: 10/05/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS104849

Study ID

104955

DARWIN EU® study

No

Study countries

Spain

Study status

Ongoing

Research institutions and networks

Institutions

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

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Institution

HSRP Unit

Contact details

Study institution contact

Clara L Rodríguez-Bernal rodriguez_claber@gva.es

Study contact

rodriguez_claber@gva.es

Primary lead investigator

Clara Rodríguez-Bernal

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/09/2022

Actual: 01/09/2022

Study start date
Planned: 01/03/2023

Actual: 02/05/2023

Date of final study report
Planned: 30/12/2025

Sources of funding

- Other

More details on funding

Agencia Estatal de investigación (National Research Agency)

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

Disease epidemiology

Drug utilisation

Main study objective:

To carry out a study on the safety of antihypetensive (AH) drugs during pregnancy, on one hand, and the role of hypertension on pregnancy outcomes, on the other, in an attempt to disentangle the effect of the medications from that of the illness itself, using for this purpose the PREGVAL cohort, constructed with data from the Valencia Health System Integrated Database (VID).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C02AB01) methyldopa (levorotatory)

methyldopa (levorotatory)

(C07AG01) labetalol

labetalol

(C08CA05) nifedipine

nifedipine

(C07AB07) bisoprolol

bisoprolol

(C01CA24) epinephrine

epinephrine

(C09CA) Angiotensin II receptor blockers (ARBs), plain

Angiotensin II receptor blockers (ARBs), plain

(C03CA01) furosemide

furosemide

(C04AD03) pentoxifylline

pentoxifylline

(C07AA05) propranolol

propranolol

(C03CA04) torasemide

torasemide

Medical condition to be studied

Pregnancy

Hypertension

Congenital anomaly

Abortion

Foetal death

Stillbirth

Population studied

Age groups

- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

600.000

Study design details

Outcomes

congenital anomalies, abortion, fetal death, stillbirth, neonatal death, Preterm birth, Small for Gestational age.

Data analysis plan

We will conduct 3 separate comparisons in our analyses: 1) women with CH exposed to antihypertensive (AH) medications during the pregnancy period vs women with CH unexposed to AH (control), 2) women with CH unexposed to AH (uncontrolled hypertension-considering blood pressure measures during pregnancy) vs. women with CH unexposed to AH (controlled hypertension-considering blood pressure measures during pregnancy) and, 3) women with CH unexposed to AH (controlled hypertension-considering blood pressure measures during pregnancy) vs. women without CH who did not receive AH medications during the pregnancy period (control). In each analysis, we first will determine the frequency of and unadjusted odds ratio (OR) and 95% confidence intervals (CIs) for the different outcomes. To account for the differences in the baseline characteristics in the groups that are being compared, we will perform propensity score analyses. Then, we will use inverse probability treatment-weighting (IPTW).

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

Electronic healthcare records (EHR)

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