Pregnancy outcome after in utero exposure to baclofen: an ENTIS collaborative study (Baclofen and pregnancy)

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Administrative details

PURI
https://redirect.ema.europa.eu/resource/16381
EU PAS number
EUPAS6934
Charles ID
Study ID
16381
DARWIN EU® study
No
Study countries
France

Germany	
☐ Israel	
Italy	
☐ Netherlands	
United Kingdom	

Study description

Objective: To evaluate the risk of early in utero exposure to baclofen and to describe neonatal symptoms after 3rd trimester baclofen exposure. Design: all prospectively assessed cases collected from 1st January 1990 up to 28th February 2012 with baclofen exposure during the first trimester of pregnancy. Study group: pregnant women exposed to baclofen between week 4 and week 12 of pregnancy and with prospectively ascertained outcome. Patients exposed to major teratogens (acitretin, isotretinoin, methotrexate, mycophenolate, thalidomide, valproic acid) or patients with malignancies or malignancy-related conditions are excluded. General control group: pregnant women exposed to a non-teratogenic agent with prospectively ascertained outcome and same exclusion criteria as above. Patients from both groups are matched according to maternal age ± 2 years, gestational age at inclusion ± 2 weeks, year of counseling \pm 2 years, TIS or country with 3 controls per case.Primary objectives: Rate of major birth defects, rate of spontaneous abortion. Secondary objectives: Intrauterine growth retardation (IUGR) in malformed and non-malformed newborns, prematurity rate (< 37 gestational weeks), rate of elective terminations of pregnancy (ETOPs). Description of postnatal symptoms. Analysis will consider counfounders with adjustments for parity, previous spontaneous abortions, previous children/fetuses with major birth defects, tobacco, alcohol intake. Statistical analysis. - Continuous endpoints comparison: Student's t test. - Categorical endpoints comparison: χ² test or Fisher's exact test when assumptions for χ^2 are not met. - If a difference is pointed out: logistic regression analysis taking into account all identified

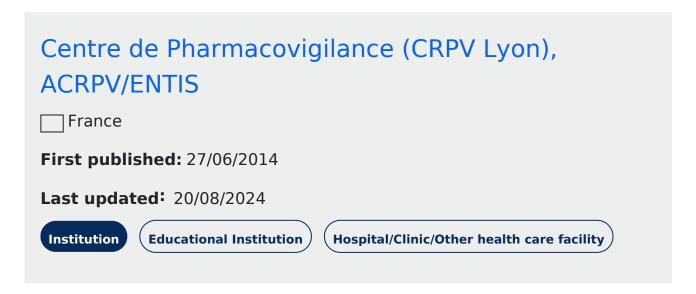
possible confounding factors. With 100 exposed cases the study has a 80% power of detecting a 3.5-fold increase in malformation rate, assuming a 3% baseline risk

Study status

Ongoing

Research institutions and networks

Institutions



Centre de Pharmacovigilance (CRPV Lyon), ACRPV/ENTIS France First published: 27/06/2014 Last updated: 20/08/2024 Institution Educational Institution Hospital/Clinic/Other health care facility

Netherlands Pharmacovigilance Centre Lareb Netherlands First published: 05/02/2010 Last updated: 19/07/2016 Institution Not-for-profit ENCePP partner



Networks



European Network of Teratology Information
Services (ENTIS)
Austria
Czechia
Finland
France
Germany
Greece
Italy
Netherlands
Spain
Switzerland
United Kingdom
First published: 31/05/2010
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Network ENCePP partner

Contact details

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Study contact

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Primary lead investigator

Nathalie BERNARD

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/12/2011

Actual: 14/12/2011

Study start date

Planned: 01/12/2012 Actual: 01/12/2012

Data analysis start date

Planned: 01/02/2013 Actual: 01/04/2013

Date of interim report, if expected

Planned: 30/04/2014 Actual: 30/04/2014

Date of final study report

Planned: 30/09/2014

Sources of funding

Other

More details on funding

Study protocol

Baclofen Protocol Final.pdf(41.11 KB)

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 assess the rate of major malformations associated with baclofen exposure during the first trimester of pregnancy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name BACLOFEN

Population studied

Age groups

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

434

Study design details

Outcomes

Rate of major malformations, Intrauterine growth retardation (IUGR) prematurity rate (< 37 gestational weeks)Rate of elective terminations of pregnancy (ETOPs). Description of postnatal symptoms after baclofen exposure throughout pregnancy

Data analysis plan

Each baclofen exposued pregnant patient is matched to 3 controls with non-teratogenic exposure, according to age, gestational age at inclusion, year of counseling, and TIS or country. Statistical analysis. - Continuous endpoints comparison: Student's t test. - Categorical endpoints comparison: χ^2 test or Fisher's exact test when assumptions for χ^2 are not met. - If a difference is pointed out: logistic regression analysis taking into account all identified possible confounding factors. - Statistical significance set at P value of less than 0.05 (two-sided). With 100 exposed cases the study has a 80% power of detecting a 3.5-fold increase in malformation rate, assuming a 3% baseline risk.

Data management

Data sources

Data sources (types)

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