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

First published: 04/07/2014

Last updated: 30/01/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/16381

EU PAS number

EUPAS6934

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 ± 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: 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.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**

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

Pharmakovigilanzzentrum Embryonaltoxikologie (Embryotox Berlin), Charité-Universitätsmedizin

Germany

First published: 22/02/2010

Last updated: 30/12/2013

Institution | Educational Institution | ENCePP partner

Networks

Association française des centres régionaux de Pharmacovigilance (ACRPV)

France

First published: 29/03/2010

Last updated: 30/09/2014

Network | ENCePP partner

European Network of Teratology Information Services (ENTIS)

- [ ] Austria
- [ ] Czechia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom

First published: 31/05/2010

Last updated: 13/05/2024

Network ENCePP partner

Contact details

Study institution contact

Nathalie BERNARD-PHALIPPON

Study contact

nathalie.bernard-phalippon@chu-lyon.fr

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

ENTIS, ACRPV

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