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

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

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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 | Outdated | Not-for-profit | ENCePP partner

Pharmakovigilanzzentrum Embryonaltoxikologie (Embryotox Berlin), Charité-Universitätsmedizin

Germany

First published: 22/02/2010

Last updated: 30/12/2013

Institution | Outdated | 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 | Outdated | 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

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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

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

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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

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)

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