# 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

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**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: $\chi^2$ test or Fisher's exact test when assumptions for $\chi^2$ 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 | 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**

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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

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**Study start date**

Planned: 01/12/2012

Actual: 01/12/2012

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**Data analysis start date**

Planned: 01/02/2013

Actual: 01/04/2013

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**Date of interim report, if expected**

Planned: 30/04/2014

Actual: 30/04/2014

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**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: $\chi^2$ test or Fisher's exact test when assumptions for $\chi^2$ 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