

# PREG-Med - Case-Control Study on the Impact of Pregnancy on Prescribing Psychotropic Medication

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| General                                                                                                                  |                                                                                      |
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| Identification                                                                                                           |                                                                                      |
| Detailed name                                                                                                            | Case-Control Study on the Impact of Pregnancy on Prescribing Psychotropic Medication |
| Sign or acronym                                                                                                          | PREG-Med                                                                             |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL                                                                                 |
| General Aspects                                                                                                          |                                                                                      |
| Medical area                                                                                                             | Geriatrics<br>Psychology and psychiatry                                              |
| Health determinants                                                                                                      | Intoxication<br>Lifestyle and behavior<br>Medicine                                   |
| Keywords                                                                                                                 | psychotropic medication prescription; post-partum; antenatal; pregnancy              |
| Scientific investigator(s)<br>(Contact)                                                                                  |                                                                                      |
| Name of the director                                                                                                     | Apter                                                                                |
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| Unit                                                                                                                     | Research Unit for Psychiatry and Psychopathology                                     |
| Organization                                                                                                             | Erasme                                                                               |
| Name of the director                                                                                                     | Becquemont                                                                           |

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| Organization                                                           | Bicêtre Hospital                     |
| Name of the director                                                   | Devouche                             |
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| Organization                                                           | Institute of Psychology              |
| Collaborations                                                         |                                      |
| Funding                                                                |                                      |
| Funding status                                                         | Public                               |
| Details                                                                | Erasme, Institute of Psychology      |
| Governance of the database                                             |                                      |
| Sponsor(s) or organisation(s) responsible                              | Erasme                               |
| Organisation status                                                    | Public                               |
| Additional contact                                                     |                                      |
| Main features                                                          |                                      |
| Type of database                                                       |                                      |
| Type of database                                                       | Study databases                      |
| Study databases (details)                                              | Case control study                   |
| Database recruitment is carried out by an intermediary                 | An administrative base or a register |
| Base or register (detail)                                              | Member of a social security scheme   |
| Database recruitment is carried out as part of an interventional study | No                                   |
| Database objective                                                     |                                      |

|                                              |                                                                                                                                                     |
|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Main objective                               | To determine if and how the prescription of psychotropic medication changes during pregnancy.                                                       |
| Inclusion criteria                           | Women covered by a social security scheme.                                                                                                          |
| Population type                              |                                                                                                                                                     |
| Age                                          | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population covered                           | General population                                                                                                                                  |
| Gender                                       | Woman                                                                                                                                               |
| Geography area                               | National                                                                                                                                            |
| Detail of the geography area                 | France                                                                                                                                              |
| Data collection                              |                                                                                                                                                     |
| Dates                                        |                                                                                                                                                     |
| Size of the database                         |                                                                                                                                                     |
| Size of the database (number of individuals) | Greater than 20 000 individuals                                                                                                                     |
| Details of the number of individuals         | 87,213 (pregnant women); 87,213 controls                                                                                                            |
| Data                                         |                                                                                                                                                     |
| Database activity                            | Data collection completed                                                                                                                           |
| Type of data collected                       | Administrative data                                                                                                                                 |
| Administrative data (detail)                 | Prescription of psychotropic medication                                                                                                             |
| Presence of a biobank                        | No                                                                                                                                                  |
| Health parameters studied                    | Health event/morbidity                                                                                                                              |
| Procedures                                   |                                                                                                                                                     |
| Participant monitoring                       | Yes                                                                                                                                                 |
| Details on monitoring of participants        | 4 months before pregnancy; 9 months during pregnancy and 4 months after pregnancy.                                                                  |

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|---------------------------------|-----|
| Links to administrative sources | Yes |
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|----------------------------------------|-----------------|
| Linked administrative sources (detail) | CRAMIF database |
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## Promotion and access

### Promotion

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| Link to the document | <a href="http://www.journal-therapie.org/articles/therapie/abs/first/therapie140012/therapie140012.html">http://www.journal-therapie.org/articles/therapie/abs/first/therapie140012/therapie140012.html</a> |
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### Access

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| Terms of data access (charter for data provision, format of data, availability delay) | Contact the scientist in charge (risk that data may be removed after two years due to lack of archiving space in a rolling system). |
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| Access to aggregated data | Access on specific project only |
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| Access to individual data | Access on specific project only |
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