Influence of social deprivation on benzodiazepines and antidepressants drugs dispensing among children and adolescents: a large cross-sectional population-based study in France

First published: 31/12/2019

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS32925

Study ID

41686

DARWIN EU® study

No

Study countries

France

Study description

In European studies, association between socio-economic indicators of precariousness and benzodiazepines misuse, or antidepressants has been found, but these studies targeted more specifically the adults. Some French studies dealing with mental health management of children were not specifically assessing the link between socioeconomic position (SEP) and psychotropic drugs use and/or adequacy as a primary objective, or SEP was not measured with an indicator specl. We assume that lower SEP is associated with an inadequacy to the recommendation of psychotropic drugs use among children and adolescent, regarding recommendations. Lower SEP should be associated with a greater number of benzodiazepines and antidepressants dispensing, at an individual level. Primary objective: To assess correlation between the number of benzodiazepines dispensing (anxiolytic and hypnotic drugs) and the European Deprivation Index (EDI). Cross-sectional population-based study, based on secondary data collection, from the joint use of the Health Insurance information system and a social deprivation index in the large French region of Midi-Pyrenees during the year 2012 will be performed. Persons, aged below 18, with the right to access, as of 31 December 2012, one of the three main health insurance schemes in the Midi-Pyrénées region of France will be included. It represents 540,295 individuals who are below 18 in the exhaustive regional database that included 2,574,310 individuals (after excluding 92,542 beneficiaries who died during the period of interest and 41,349 beneficiaries to whom no IRIS could be allocated) We will perform a comparative analyses between groups, an - Univariate analyses and multivariate analyses (linear regression) of the association between the number of benzodiazepines drugs dispensed and covariates. We expect to find an association between a higher social deprivation index and number of benzodiazepines and antidepressants dispensed at an individual level.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

France

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

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Primary lead investigator

Marie-Eve Rougé-Bugat

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 10/12/2018

Study start date
Planned: 15/01/2020

Actual: 15/01/2020

Data analysis start date
Planned: 15/01/2020

Actual: 28/01/2020

Date of final study report
Planned: 15/09/2020

Actual: 16/06/2021

Sources of funding

- Other

More details on funding

Self funding

Study protocol

Research protocol-2.pdf (524.17 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess correlation between the number of benzodiazepines dispensing (anxiolytic and hypnotic drugs) and the European Deprivation Index (EDI).

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05) PSYCHOLEPTICS

PSYCHOLEPTICS

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

Population studied

Short description of the study population

Inclusion criteria:

Every beneficiary, ages below 18, from the National Healthcare Insurance with the right to access, in one of the three main health insurance schemes (General Regime (RG),

Mutualité Sociale Agricole (MSA) and the Social Regime of Independents (RSI)) from the MidiPyrénées region of France were included, regardless of the age or gender. These 3 main schemes include 87% of the total region’s population.

Exclusion criteria:

- Some populations have been excluded due to the differences in the management of the beneficiaries: the local mutual sections for the RG, the grouping of the health insurers of the operators for the MSA and self-employed professions for the RSI
- People who died during the period of interest

- Beneficiaries to whom no IRIS could be allocated (specific codes and data related to more than 50,000 districts, built by the National Institute of Statistics and Economic Studies)

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

540.295

Study design details

Outcomes

Correlation between EDI and number of distinct benzodiazepine drugs (ATC: N05) dispensing. Correlation between EDI and number of distinct antidepressant drugs (ATC: N06A) dispensing (in both subgroups of children below 12 and adloescent above 12). Adequacy with guidelines regarding antidepressants drug dispensing patterns.

Data analysis plan

Descriptive analysis. Comparative analyses between groups (depending on EDI assessment, psychotropic drug or mental healthcare use levels) with Chi2 (or exact Fisher tests if not applicable) for categorical variables, and Student’s T test (or non-parametrical test if not applicable) or variances analyses (ANOVA for continuous variables, when relevant). p-value <0.05 will be considered as statistically significant. Univariate analyses (linear regression) of the association between the number of drugs dispensed, for each class of drugs (antidepressants, anxiolytics and hypnotics) and the EDI and other covariates,

will be performed. Then, a multivariate analysis (linear regression), will be performed. A multivariate analysis will also be performed on secondary outcomes (antidepressants) and the subgroups of children below and above 12. Sensitivity analyses, regarding association between EDI or HP and levels or number of psychotropic drugs dispensing by classes of drugs.

Documents

Study results

ENCEPP-jech-2021-217524_Proof_hi.pdf (81.42 KB)

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

EUPAS32925_COI.pdf (1.63 MB)

Composition of steering group and observers

EUPAS32925-32960.pdf (361.09 KB)

Signed code of conduct

ENCePPCoCAnnex3_DeclarationofcompliancewiththeENCePPCodeofConduct(1).pdf (744.16 KB)

Signed code of conduct checklist

ENCePPCoCAnnex2_ChecklistofCodeofConduct(1).pdf (926.83 KB)

Signed checklist for study protocols

ENCePPChecklistforStudyProtocolsRevision.pdf (270.93 KB)

ENCePPChecklistforStudyProtocolsRevision-signedDD.pdf (387.35 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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