PRJ2215: Assessment of Bupropion Misuse/Abuse 2004-2011 (201235)

First published: 17/01/2014

Last updated: 24/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5568

Study ID

48174

DARWIN EU® study

No

Study countries

☐ United States

Study description

The objective of this study is to examine the degree of misuse and abuse of bupropion using the Drug Abuse Warning Network Database. Objectives are as follows: 1. To examine the number of bupropion reports over time within the

DAWN database and to draw a comparison against the number of all DAWN reports for prescription drugs. 2. To examine the number of reports for bupropion, stratified by demographics, route of administration, and disposition of the patient.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/12/2013

Actual: 03/12/2013

Study start date
Planned: 03/12/2013

Actual: 22/11/2013

Data analysis start date
Planned: 03/12/2013

Actual: 03/12/2013

Date of final study report
Planned: 31/03/2014

Actual: 16/06/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

epi prj2215-protocol-redact.pdf(341.3 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Assessment of bupropion abuse potential

Data collection methods:

Primary data collection

Main study objective:

1. To examine the number of bupropion reports over time within the DAWN databse and to describe the number of all DAWN reports for prescription drugs. This is analogous to the disproportionality analysis conducted within GCSP for the evaluation of safety signals.2. To examine the number of reports for bupropion, stratified by demographics, route of administration, and disposition of the patient

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective analysis of surveillance data reported in DAWN between 2004 and 2011.

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

BUPROPION

Population studied

Short description of the study population

The study population includes patients of all ages presenting to emergency departments for drug-related causes. The DAWN visit eligibility criteria are intended to be broad and inclusive and to have few exceptions. They take into account the fact that documentation in medical records varies in clarity and completeness across hospitals and among clinicians within hospitals. The criteria are designed to minimize the potential for DAWN Reporter judgments that could cause data to vary systematically and unexpectedly across different data collectors and hospitals. In addition, the criteria allow for the capture of a diverse set of drug-related visits that can be aggregated or disaggregated to serve a variety of analytical purposes and the interests of multiple audiences. There are a few clearly delineated exceptions to the DAWN eligibility criteria. An ED visit is not a DAWN visit if

- there is no evidence of recent drug use;
- the patient left the ED without being treated;
- the patient consumed a nonpharmaceutical substance but did not inhale it;
- the patient has a history of drug use but no recent use;
- alcohol is the only substance involved, and the patient is an adult (aged 21 or older);
- all the drugs mentioned in the ED record are not related to the ED visit (e.g., list of current medications);
- drugs identified in toxicology testing are not related to the visit, and the medical record does not contain any additional drug-related information that would make
the visit a DAWN case; or
- the patient is being treated as a consequence of undermedication (i.e., taking too little of a drug).

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

0

Study design details

Data analysis plan

Data on all reports of prescription drug misuse and abuse will be captured using the DAWN data sets from years 2004 to 2011, examined by year individually. Data on all reports of bupropion misuse and abuse will be captured using the same data. These data will include reports of bupropion without mention of any other drug. However, such reports will also be analysed as a separate category. Percent change will be evaluated for each year, as compared to the previous year. For each year in the study period, 2004-2011, a distribution of patient characteristics as well as case type and patient disposition will be captured in tables. These tables will note the number of patients in the DAWN dataset (unweighted) as well as weighted N and weighted percentages of all the bupropion reports.

Documents

Study results

gsk-PRJ2215-clinical-study-report-redact.pdf(596.7 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.

Data sources

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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