ZYB117211: Plan to Assess the Incidence of Cardiovascular Related Adverse Events in Controlled Clinical Trials of Bupropion for the Treatment of Smoking Cessation

First published: 21/05/2014

Last updated: 24/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6441

Study ID

48168

DARWIN EU® study

No

Study countries

United States

Study description

The proposed investigation will evaluate the incidence of cardiovascular related deaths and serious and non-serious adverse cardiovascular events in randomized clinical trials of Bupropion marketed as Zyban (ZYB) for smoking cessation

Study status

Finalised

Research institutions and networks

Institutions

Duke Clinical Research Institute (DCRI)

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: 31/10/2013

Actual: 31/10/2013

Study start date
Planned: 17/12/2013

Actual: 15/02/2013

Data analysis start date
Planned: 24/03/2014

Date of final study report
Planned: 27/06/2014

Actual: 27/06/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The objective of this investigation is to compare the incidence of adverse cardiovascular events in Zyban treated groups versus control groups in

previously completed randomized clinical trials of smoking cessation treatment.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

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

BUPROPION

Medical condition to be studied

Cardiovascular insufficiency

Population studied

Short description of the study population

Subjects from GSK sponsored randomized controlled trials who took at least one dose of the Bupropion marketed as Zyban (ZYB) for smoking cessation.

Age groups

- 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

10.640

Study design details

Outcomes

The primary endpoint is the time to an on-treatment MACE event, Incidence of MACE, incidence of components of MACE event, Incidence of MACE+ event, Incidence of components of MACE+ event, Incidence of other events of interest,Time to MACE+

Data analysis plan

The time-to-MACE will be analyzed using log-rank test. The survival distribution of the time to first on-treatment MACE will be compared between treatment groups via a stratified log-rank test with Study as a stratification variable.

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

Retrospective data from completed clinical trials.

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