Prevalence and Incidence of Problematic Prescription Opioid Use and Abuse in the United Kingdom and Germany (OXY9504)

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Administrative details

PURI

https://redirect.ema.europa.eu/resource/17996

EU PAS number

EUPAS10129

Study ID

17996

DARWIN EU® study

No

Study countries

Germany

United Kingdom

Study status

Finalised

Research institution and networks

Institutions

Real World Evidence Solutions, IMS Health

France

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Contact details

Study institution contact

Cooper Andrew

Study contact

andrew.cooper@mundipharma-rd.eu

Primary lead investigator

Joseph Kim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/11/2013 Actual: 02/12/2013

Study start date

Planned: 11/03/2014 Actual: 08/04/2014

Data analysis start date

Planned: 25/05/2015

Date of final study report

Planned: 25/05/2016 Actual: 27/06/2016

Sources of funding

• Pharmaceutical company and other private sector

More details on funding

Mundipharma Research Ltd

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Quantify problematic prescription use and abuse of prescription opioids in Germany and the United Kingdom

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02A) OPIOIDS

OPIOIDS

Medical condition to be studied

Drug abuse

Population studied

Short description of the study population

Patients with opioids use in the UK and Germany.

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

180000

Study design details

Outcomes

Incidence and 5-year prevalence of problematic prescription use and abuse of prescription opioids from 2008-2012, Characterisation of the abusing and non-abusing population: demographics, drug utilisation.

Data analysis plan

Calculation of incidence rate and 5-year prevalence of problematic use of prescription opioids per molecule from 2008 to 2012.

Data management

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

Electronic healthcare records (EHR)

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

Unknown