Over the Counter Codeine Use Misuse and Dependence (CODEMISUSED)

First published: 17/09/2013

Last updated: 22/02/2024

Study Planned

Administrative details

EU PAS number

EUPAS4708

Study ID

6910

DARWIN EU® study

No

Study countries

Ireland

South Africa

United Kingdom

Study description

The research aims to quantify the extent of codeine use, misuse and dependence in three countries (Ireland, United Kingdom and South Africa), with focus on therapeutic and non-therapeutic use, so as to create user profiles of use and abuse and capture individual user, pharmacy, medic and treatment provider perspectives. Data will be used to inform the design of pharmacy based brief interventions and customer monitoring systems, continuing staff training and management of appropriate treatment interventions. A mixed method approach will commence with a meta-analysis and systematic review of literature, which along with national pharmacist, medic and treatment provider surveying, will inform the design and implementation of sweep surveys of individuals purchasing OTC codeine in pharmacies, internet based codeine user focus groups targeting web based sales and use, and interviews with codeine users, mis-users and dependents in each country.

Study status

Planned

Research institutions and networks

Institutions

Waterford Institute of Technology

First published: 01/02/2024

Last updated: 01/02/2024

Institution

School of Health Sciences, Waterford Institute of Technology (WIT)

Ireland

First published: 17/09/2013

Last updated: 20/08/2024

Institution | Educational Institution

King's College London

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Waterford Institute of Technology, School of Health Sciences Ireland, South African Medical Research Council, Alcohol and Drug Abuse Research Unit South Africa, Kings College London United Kingdom

Contact details

Study institution contact

Marie Claire Van Hout mcvanhout@wit.ie

Study contact

mcvanhout@wit.ie

Primary lead investigator

Marie Claire Van Hout

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/08/2013

Study start date

Planned: 01/09/2013

Data analysis start date

Planned: 01/12/2013

Date of interim report, if expected

Planned: 01/09/2015

Date of final study report

Planned: 01/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

FP7-PEOPLE-2013-IAPP (Marie Curie)

Study protocol

ANNEX START UP.pdf (1.16 MB)

Annex May 13th 2014.pdf (1.46 MB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The research aims to quantify the extent of codeine use, misuse and dependence in three countries (Ireland, United Kingdom and South Africa), with focus on therapeutic and non-therapeutic use, so as to create user profiles of use and abuse and capture individual user, pharmacy, medic and treatment provider perspectives.

Study drug and medical condition

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

CODEINE

Population studied

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

9.500

Study design details

Outcomes

National, international reports, journal publications, public fact sheets, seminars, conference proceedings reflecting outputs from meta-analysis and systematic review of literature, national pharmacist, medic and treatment provider surveying, customer sweep surveys internet based codeine users and interviews with codeine users. Data will be used to inform the design of pharmacy based brief interventions for codeine misuse, inter pharmacy customer monitoring and tracking systems, continuing staff training (CPD) and management of appropriate codeine referral and treatment interventions.

Data analysis plan

Risk estimation: A mixed method approach will commence with a meta-analysis and systematic review of literature, national pharmacist, medic, treatment provider and customer surveying analysed with SPSS, internet surveillance and codeine user interviews and focus groups analysis assisted by NVIVO

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.

Composition of steering group and observers

ABSTRACT WITH PARTNER LISTING.pdf (336.39 KB)

Data sources

Data sources (types)

Drug dispensing/prescription data

Spontaneous reports of suspected adverse drug reactions

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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