# Over the Counter Codeine Use Misuse and Dependence (CODEMISUSED)

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## 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

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

☐ Ireland

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Institution

**Educational Institution** 

## King's College London

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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**

9500

## 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