Benzodiazepine and anticholinergic use and incident dementia (ABCD study)

First published: 09/11/2015

Last updated: 18/12/2018

Study Ongoing

Administrative details

EU PAS number

EUPAS8705

Study ID

27156

DARWIN EU® study

No

Study countries

United Kingdom

Study description

In this study we will examine whether the use of benzodiazepines, non-benzodiazepine derivates and medications with anticholinergic activity increase the risk of dementia. We will also examine whether the risk persists or is

reduced once the medication is stopped. We will identify CPRD patients who, since April 2006, were diagnosed with dementia aged 65-99 years. We will compare the medication history of each patient with dementia to that of 7 matched patients without dementia. We will compare the use and dosage of medications prescribed during the period before dementia diagnosis, whilst controlling for other health and social differences.

Study status

Ongoing

Research institutions and networks

Institutions

University of East Anglia

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Institution

Contact details

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Primary lead investigator

Savva George

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 30/06/2014

Study start date
Actual: 03/07/2015

Data analysis start date
Planned: 24/08/2015

Actual: 26/10/2015

Date of final study report
Planned: 30/09/2018

Sources of funding

- Non-for-profit organisation (e.g. charity)

More details on funding

Alzheimer's Society

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 type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

1. To determine whether the use of benzodiazepines, non-benzodiazepine derivatives or medications with anticholinergic activity increases the risk of dementia, and whether risk increases with increased duration, dosage or concurrent use.2. To determine whether these effects persist beyond medication cessation.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05BA) Benzodiazepine derivatives

Benzodiazepine derivatives

(N05CD) Benzodiazepine derivatives

Benzodiazepine derivatives

(N05CF) Benzodiazepine related drugs

Benzodiazepine related drugs

(N04A) ANTICHOLINERGIC AGENTS

ANTICHOLINERGIC AGENTS

Medical condition to be studied

Dementia

Population studied

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

326.000

Study design details

Outcomes

Dementia incidence

Data analysis plan

We will assess the association between benzodiazepine exposure, anticholinergic exposure and dementia using conditional logistic regression. Odds ratios (and 95% confidence intervals) will be provided unadjusted and adjusted for exposure to each class of medications with adverse cognitive effects and covariates. The association between dementia and the primary exposure of DDDs will be examined, for (i) benzodiazepines, (ii) Z-drugs, and medications with (iii) possible, (iv) probable and (v) definite anticholinergic activity. The model will adjust for the covariates as well as the number of DDDs of the other medications with potential adverse cognitive effects.The association between dementia and the following secondary exposures will be separately examined:• Duration of prescriptions. • Any prescription. • For anticholinergics - average ACB sum and duration taking 3 or more possible anticholinergics concurrently.

Documents

Study publications

Richardson K, Fox C, Maidment I, et al. Anticholinergic drugs and risk of demen…

Data management

Data sources

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

No