Overactive bladder anticholinergics and risk of incident dementia: a cohort study design using a triangulation approach

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Study Ongoing

Administrative details

EU PAS number

EUPAS43447

Study ID

43448

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Overactive bladder is increasingly common as people age and can severely affect quality of life. It is often treated with medications called ‘anticholinergics’ or ‘antimuscarinics’, but some studies have associated these with memory problems and a higher risk dementia if used for a long time. However, we don’t know whether these medications actually cause this increased risk or are simply used more often in people already at risk of dementia. We also don’t know how the risk varies among different patient groups or types of anticholinergics. Data from medical records are increasingly used for dementia research, but there are challenges in their use. Dementia diagnoses can be delayed, not made at all, or not promptly communicated across healthcare services, so this needs careful analysis. We will analyse the general practitioner (GP) and hospital records of >700,000 patients aged ≥50 years in England prescribed bladder anticholinergics. We will examine whether, all other factors being equal, patients taking long-term bladder anticholinergics develop dementia more often than patients with only a single prescription. We will then estimate how this risk varies by duration of treatment, for specific patient groups, and for specific bladder drugs. As we also don’t fully understand how these medications affect the brain, we will also examine whether delirium or fractures are more common with longer term use of bladder anticholinergics.

Study status

Ongoing

Research institutions and networks

Institutions

University of East Anglia

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Richardson Kathryn

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/01/2019

Actual: 04/01/2019

Study start date

Planned: 14/01/2021

Actual: 14/01/2021

Data analysis start date

Planned: 04/10/2021

Date of final study report
Planned: 17/08/2023

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

Drug utilisation

Main study objective:

To examine whether recurrent overactive bladder anticholinergic prescriptions are associated with increased dementia incidence versus receiving one prescription (separately in men and women).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G04BD) Drugs for urinary frequency and incontinence

Drugs for urinary frequency and incontinence

Medical condition to be studied

Hypertonic bladder

Population studied

Age groups

- Adults (46 to < 65 years)

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

Estimated number of subjects

1.300.000

Study design details

Outcomes

Time to dementia diagnosis, delirium, fracture, stroke, motor vehicle accident

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Data analysis plan

New user design cohort studies of patients in England prescribed OAB medications since 1998. Dementia incidence (using Clinical Practice Research Datalink, Hospital Episode Statistics and Office for National Statistics mortality data) will be compared after applying a 3-year lag period between patients receiving a second OAB prescription to those only receiving one prescription using Cox regression with age as the time-scale. We are using a triangulation approach, hence performing various analyses to see if the findings are consistent with causality and examine confounding and selection biases. This includes additionally examining the outcomes of delirium, fractures and stroke (primarily with exposure as time-varying and no lag period).

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Hospital Episode Statistics

Data source(s), other

CPRD, HES

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