

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

**First published:** 04/10/2021

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS43447

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### Study ID

43448

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### 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  $\geq 50$  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.

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### **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

[kathryn.richardson@uea.ac.uk](mailto:kathryn.richardson@uea.ac.uk)

### Primary lead investigator

Richardson Kathryn

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 04/01/2019

Actual: 04/01/2019

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### Study start date

Planned: 14/01/2021

Actual: 14/01/2021

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### Data analysis start date

Planned: 04/10/2021

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## 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

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### Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Methodological aspects

### Study type

### Study type list

#### Study type:

Non-interventional study

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**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

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**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)
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### **Estimated number of subjects**

1300000

## 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

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.

## Data sources

### Data source(s)

Clinical Practice Research Datalink

Hospital Episode Statistics

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### Data source(s), other

CPRD, HES

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No