# Intended and unintended effects of Z-drug use for sleep disturbance in people with dementia – ‘Z-drug Evaluation in Dementia’ (ZED)

**First published:** 28/03/2017

**Last updated:** 28/03/2017

Study Ongoing

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/18007

**EU PAS number**

EUPAS18006

**Study ID**

18007

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

Sleep disturbance is common in dementia, and can severely affect patient and carer quality of life. Z-drugs (zolpidem, zaleplon and zopiclone) are sedating hypnotics that are used for insomnia in older people and in people with dementia. Current guidance suggests Z-drugs or short acting benzodiazepines (BZD) can relive sleep disturbance and can provide respite for carers. Nevertheless there are concerns about tolerance, addiction and the safety of Z-drugs, with adverse effects including increases in falls and fracture risk, impaired daytime cognition, and higher risks of infections. Other sedating neuroleptics are known to increase stroke risk and mortality, with mediating pathways including dehydration and over-sedation and it is important to confirm whether Z-drugs confer similar risks.Our aim is to understand the benefits and harms of using Z-drugs for people with dementia who have trouble sleeping. Using data from the Clinical Practice Research Datalink we will look at whether people with dementia who take Z-drugs fall more often, have more infections or are taken to hospital more often among other health outcomes. We will compare Z-drugs to other sleep drugs prescribed to people with dementia, and to people who do not use any sleep medication at all.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

# University of East Anglia

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

George Savva

Study contact

G.Savva@uea.ac.uk

### Primary lead investigator

George Savva

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 23/02/2016

### Study start date

Actual: 01/06/2016

### Data analysis start date

Planned: 01/06/2017

**Date of final study report**
Planned: 01/12/2017

## Sources of funding

- Other

## More details on funding

National Institute for Health Research, University of East Anglia

## Study protocol

CPRD ISAC_ZED_R1_180117.pdf(521.67 KB)

## 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

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

Using existing data we will look at whether Z-drugs improve sleep, whether they improve quality of life for people with dementia and their carers and how they affect memory and thinking during the day or other behavioural problems.

## Study Design

**Non-interventional study design**

Cohort

Case-control

Cross-sectional

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N05CF) Benzodiazepine related drugs

Benzodiazepine related drugs

---

**Medical condition to be studied**

Dementia

Insomnia

## Population studied

**Age groups**

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

---

**Estimated number of subjects**

21000

## Study design details

**Outcomes**

Incident (a) fracture (any location) (b) hip fracture (c) forearm fracture. Hip fracture recording in CPRD has been well validated (PPV of 91%).Incident fall. GP records of falls may under-represent all falls that occur in the older population, but more accurately represent ‘injurious falls requiring medical attention’. Mortality.Infection. Respiratory tract infection has been validated in CPRD (PPV of 97%).

---

**Data analysis plan**

We will use the Cox proportional hazard model to estimate the effect of covariates on time to first prescription of each class sleep medication since dementia diagnosis. Sleep medication will be treated as a time-varying variable. Then we will use the multinomial regression model to estimate the effect on treatment choice conditional on the sleep disturbances, after controlling for potential confounders, allowing non-linear effects and interaction between confounding variables and time-varying ones.

## Data management

**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