Estimating the benefits and harms of Z-drugs for people with dementia and sleep disorders

https://www.neurodegenerationresearch.eu/survey/estimating-the-benefits-and-harms-of-z-drugs-for-people-with-dementia-and-sleep-disorders/

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United Kingdom

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Estimating the benefits and harms of Z-drugs for people with dementia and sleep disorders

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1.5

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Research Abstract

Background and rationale The class of hypnotic drugs known as Z-drugs (zolpidem, zopiclone and zaleplon; henceforth Zs) are effective for insomnia in the older population but are associated with a spectrum of adverse events including falls, fracture, daytime cognitive impairment and infection. Insomnia and other sleep disturbance is common in people with dementia (PwD) and severely affects quality of life for PwD and carers. Zs are commonly used in dementia as there are few alternative treatments. The nature of the suspected harms of Zs in the general older population suggest that they might be particularly harmful for PwD, but their safety and efficacy has not been evaluated in this group. There is an urgent need to understand

the benefits and harms of Zs in PwD, given the importance of Zs in offering respite from sleep disturbance for patients and cares, and the severity of the supposed harms. Study Design We will use existing data to estimate the impact of Z use on adverse events as well as cognitive function, functional ability and quality of life in PwD. Data sources include (i) the Clinical Practice Research Datalink (CPRD which includes data routinely recorded by GPs) and (ii) pooled data from clinical studies including randomised controlled trials (RCTs) and clinical cohorts including people with dementia (PwD). These data sources are complementary and together enable us to fully meet the HTA commissioning brief. First, an inception cohort of around 14,000 PwD and new sleep disturbance will be identified within CPRD. The effect of exposure to Z on the rate of a range of adverse outcomes will be estimated, compared to the effects of other treatments or no treatment. Second, we will harmonise data from around 5,000 PwD recruited to clinical studies. We will use this data to estimate the effect of Z on a range of patient and carer reported outcomes. We will carefully control for potentially confounding covariates and the nature and severity of sleep disturbance. Exposures and comparators We will estimate the effect of Zs compared to other commonly used treatments (in particular benzodiazepines) and to those with no pharmacological treatment. Outcomes Exact outcomes will be prioritised by stakeholders with input from clinicians, care workers and people affected by dementia. Outcomes from CPRD will include falls and fractures, infections, stroke, neuropsychiatric symptoms, healthcare contacts and mortality. Outcomes from RCTs will include changes in cognition and function, changes in sleep disturbance and carer and patient quality of life. Sample size CPRD includes 14,000 PwD with sleep disturbance. Clinical studies together include 5000 PwD, with an estimated prevalence of sleep disturbance in dementia of around 60%. Timelines The project will begin in June 2016 and run for 18 months: Months 1-6. Develop protocols and extract CPRD data; Harmonise and RCT and cohort data. Months 7-18. Analysis and dissemination activity. Expertise Our team includes all necessary expertise: statistics/pharmacoepidemiology (Savva/Richardson/Loke), nursing and dementia care (Arthur), primary care (Steel), pharmacy (Maidment), pharmacology (Loke) and old age psychiatry (Howard/Ballard/Fox). PPI representatives from INSPIRE (a PPI group with a specific interest in mental health and dementia research) will contribute to prioritisation of outcomes, interpretation and dissemination.

Further information available at:

http://www.nets.nihr.ac.uk/projects/hta/1422102

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