HTA study of antidepressants for depression in dementia – a definitive multicentre pragmatic randomised controlled trial of clinical and cost effectiveness (HTA-SADD)

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Title of project or programme

Title of PI	HTA study of antidepressants for depression in dementia – a definitive multicentre pragmatic randomised controlled trial of clinical and cost effectiveness (HTA-SADD)

Principal Investigators of project/programme grant

Title	Forname	Surname	Institution	Country
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- United Kingdom

Source of funding information

Department of Health (DH)

Total sum awarded (Euro)

2210588

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01-09-2006

Total duration of award in months

55

The project/programme is most relevant to

- Alzheimer's disease and other dementias

Keywords

Alzheimer Disease, Dementia

Research abstract in English

HTA-SADD is a multi-centre, double-blind, randomised controlled trial to determine the clinical and cost effectiveness of two classes of antidepressant for depression in dementia. The trial is organised by Professor Sube Banerjee at the Institute of Psychiatry, King's College London, with nine centres across England. A sample of 507 participants diagnosed as having depression as well as dementia will be randomly allocated to sertraline, mirtazapine or placebo on a 1:1:1 ratio. The study treatment will be taken for a period of ten months. It is a pragmatic trial designed for case inclusion as representative as possible of clinical practice. All participants will have a nominated carer who will act as informant and supervise adherence to the prescribed treatment regimen. Assessment is scheduled at 13 and 39 weeks, to estimate short-term and long-term effects, with scores on Cornell Scale for Depression in Dementia as the primary outcome measurement. Secondary outcome measurement will include adverse treatment events, severity of dementia, neuropsychiatric symptoms, activities of daily living, physical illness, service receipt and carer burden. Results will be generated by analysis of co-variance of Cornell scores and economic analysis.

Lay summary

There is an increasing awareness of importance of depression in dementia, causing lower quality of life for patients, increased burden upon carers, and referral to specialist mental health services. A recent Cochrane review has found the evidence base for antidepressant treatment of such cases is weak with few high quality trials. Not only is there little evidence-based guidance for clinicians as to what treatments are optimal, there is little convincing evidence that treatments are more effective than placebo. We propose a trial which can truly take the evidence base and clinical practice forward. A placebo group is not just ethical, but probably essential in current circumstances. If antidepressants are indeed not effective, then this group may do better as they should have fewer side effects. Further unanswered questions concern what class of antidepressant to choose and how long to treat.

This trial is designed to provide best-quality data on all these clinically important areas. Consultation with patients and clinicians have led us to conclude that it would not be acceptable to randomise people with dementia to medication with a predictable set of negative (anticholinergic eg constipation, increased confusion, blurred vision, low blood pressure, drowsiness) side effects. We have therefore not included a tricyclic antidepressant arm but instead will compare the clinical and cost effectiveness (including discontinuation and adverse effects) of the two classes of antidepressants most in use. We will recruit 507 patients with depression in dementia and randomise them to receive placebo, sertraline or mirtazipine in a 1:1:1 ratio. They will be followed up at 3 and 9 months (13 and 39 weeks) and depression measured in each group to see if the treatments have helped. We will also compare the costs of the drugs and their effect on quality of life and other symptoms for the person with dementia and their carers.

In which category does this research fall?

- Clinical research