alzheimer's association®
Alzheimer's & Dementia®
THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION

< Previous Article | July 2014 Volume 10, Issue 4, Supplement, Page P273 | Next Article >

THE SAFETY AND TOLERABILITY OF ETANERCEPT IN ALZHEIMER'S DISEASE (STEADI-09): A PHASE II DOUBLE BLIND RANDOMISED PLACEBO CONTROLLED TRIAL

Clive Holmes, Joe Butchart, Laura Wolfe, Lyn Davies, Suzanne Dodge, Isobel Lewsey, Brady McFarlan, Margaret Nicholls, Hugh Perry, Ceri Rayner, Saif Sheram, Richard Sharples, Rebecca Sussams, Annette Stevens, Jessica Teeling, Vivienne Hopkins
O4-11-02

DOI: http://dx.doi.org/10.1016/j.jalz.2014.04.446

Article Info

Abstract | Full Text

Background: We have previously shown that acute and chronic systemic inflammation, associated with modest increases in peripheral levels of Tumour Necrosis Factor α (TNFα), is associated with an increased decline in cognition and an exaggeration of neuropsychiatric symptoms in subjects with Alzheimer's Disease. We hypothesised that the use of a TNF α receptor blocker (Etanercept) might, if safe and well tolerated, be worth examining for beneficial cognitive and behavioural outcomes in an AD population.

Methods: Patients with mild to moderate AD were randomised to subcutaneous Etanercept (50mg) once weekly or to identical placebo (water) over a 6 month period with a one month wash out. Safety and tolerability of this medication was recorded with secondary exploratory outcomes of cognition (ADAS-COG; MMSE), behaviour (NPI); activities of daily living (BADLS) and clinical and carers global impressions of change measured at baseline; 3 months and 6 months.

Results: 67 patients were screened of whom 26 failed to meet the inclusion or exclusion criteria (most exclusions were due to prior TB exposure). 41 subjects were randomised (20 Etanercept and 21 Placebo). Etanercept was well tolerated by this group with few adverse events or safety concerns. Two subjects from the Etanercept arm and six from the placebo arm failed to complete the study. Subjects in the placebo arm showed evidence of a greater rate of decline in measures of cognition, behaviour and activities of daily living compared with subjects in the Etanercept arm at 6 months who remained largely unchanged compared with baseline measures.

Conclusions: This study shows good tolerability and safety of Etanercept in the subjects with Alzheimer's Disease. This study is also supportive of beneficial cognitive, behaviour and activities of daily living in subjects taking subcutaneous Etanercept.