MEDICAL NUTRITION IN ALZHEIMER'S DISEASE: BASELINE CHARACTERISTICS OF 3 SOUVENAID® CLINICAL TRIALS

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Introduction: Scientific evidence indicates a clear role of nutrition in the development and progression of AD. The multi-nutrient drink Souvenaid®¹ contains a specific combination of nutrients (Fortasyn™ Connect), developed to improve synapse formation in AD patients. A proof-of-concept study (Souvenir I) with 212 drug-naïve mild AD patients showed that Souvenaid improved delayed verbal memory.

Aims: To further provide evidence for the efficacy and safety of Souvenaid, 3 randomised double-blind controlled studies were designed and started in 2009.

Methods: In the US, the ‘S-Connect’ study (NTR1683), a 24-week study in mild-to-moderate AD patients (MMSE 14-24) using AD medication started in 48 centers assessing the effect on cognitive performance (ADAS-cog). In Europe, 2 studies started: The ‘Souvenir II’ study (NTR1975), a 24-week study in drug-naïve mild AD patients (MMSE ≥20) in 27 centers assessing the effect on memory performance (Neuropsychological Task Battery [NTB]) and the EU-funded ‘LipiDiDiet’ study (NTR1705), a 24-month study in 300 prodromal AD patients assessing the effect on memory performance (modified-NTB).

Results: Enrolment for both the S-Connect and Souvenir II study was completed by end 2010. A total number of 526 patients are randomised in the S-Connect study and 259 patients in the Souvenir II study. The baseline characteristics of the Souvenir I, Souvenir II and S-Connect studies will be presented.

Conclusions: To further provide evidence for the benefits of Souvenaid, 3 large randomized double-blind placebo-controlled trials started in 2009. First results are expected to be available in 2011.

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