RANDOMISED PILOT STUDY ON THE FEASIBILITY OF ENOXAPARIN TREATMENT IN ALZHEIMER’S DISEASE

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Introduction: Accumulating evidences indicate that Aβ triggers neurotoxicity, oxidative stress and inflammatory processes that are associated with the Alzheimer disease (AD) pathology. We have previously shown that clinically relevant dose of Enoxaparin significantly lowered the Aβ cortical concentration, and reduced the number of activated astrocytes surrounding Aβ plaques in AD animal model.

Aim: In this study, we tested the safety and tolerability, and measured cerebrospinal fluid (CSF) Aβ[1-42], tau and p-tau levels at baseline and after a 3-month Enoxaparin treatment in AD patients.

Methods: Thirty patients with mild to moderate AD were randomised in two arms: Donepezil+Enoxaparin or Donepezil alone. Enoxaparin (4000 anti-factor Xa units) was administered sub-cutis once a day for 3 months.

Results: None of the subjects had either side effects or major adverse reactions. In respect to controls patients in the Enoxaparin arm showed a trend towards increased CSF mean Aβ[1-42] levels after treatment, and CSF Aβ[1-42] levels increased over time in 11 patients out of 15 (73%), whereas in control patients Ab levels were increased in 5 patients out of 14 (35%) only. At the opposite there was a trend of reduction in the rate of change in total tau (tau) and phosphorylated tau (Ptau) in the Enoxaparin group.

Conclusion: This pilot study show that long-term therapy with Enoxaparin is safe and feasible in subjects with AD. Whether determination of CSF parameters (Aβ1-42, Tau and P-Tau) could be predictive of a possible clinical efficacy of Enoxaparin in AD will be evaluate in a larger population.