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AMILORIDE CLINICAL TRIAL IN OPTIC NEURITIS: TRIAL PARADIGM

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10.1136/jnnp-2014-309236.129

Aims

1. To outline the use of Optic Neuritis as a model for neuroprotective trials
2. To present baseline clinical data on the first 14 participants within the ACTION trial.

Methods ACTION is a phase II randomised controlled trial of amiloride vs placebo in patients with acute optic neuritis, recruited within 28 days of onset. The primary outcome measure is comparison of 6 month retinal nerve fibre layer thickness between the affected and unaffected eye. Participants undergo OCT and GDx, high and low contrast visual acuity, colour vision, Humphrey visual fields, PERG, VEP, and MRI brain.

Results 14 patients have been recruited from 47 referrals. Mean time from onset of symptoms to commencing the study drug is 14.7 days, median 13. Mean visual acuity in the affected eye is 50 letters (6/60), median 64 (6/30). 7 patients had T2 white matter lesions on baseline MRI imaging. One patient had a pre-existing diagnosis of multiple sclerosis.

Conclusions Recruiting to clinical trials in acute optic neuritis is challenging but feasible. Ongoing and future neuroprotective trials in optic neuritis require a robust and motivated network of clinicians and researchers recognising the “window of opportunity” to facilitate timely referral.