Visual Outcome Measures in the Phenytoin Trial

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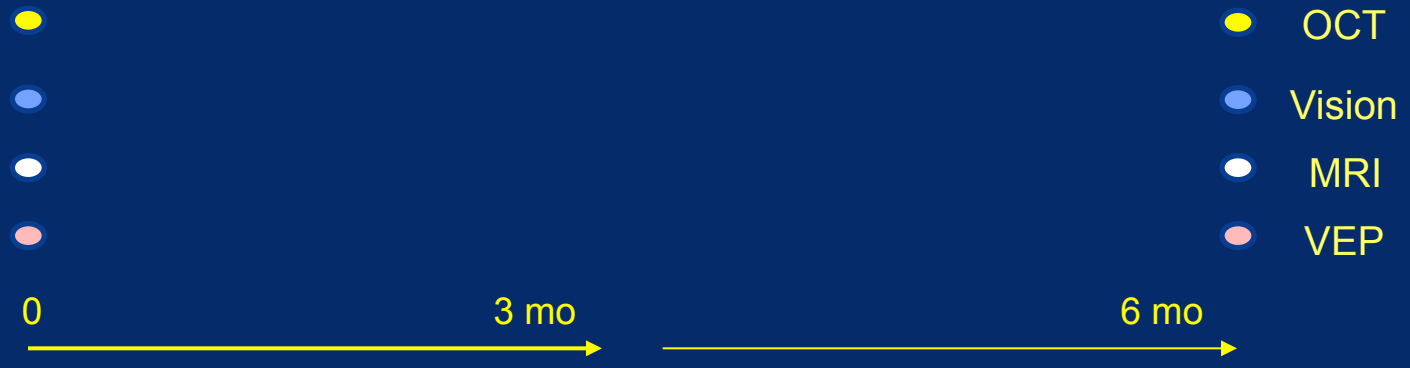
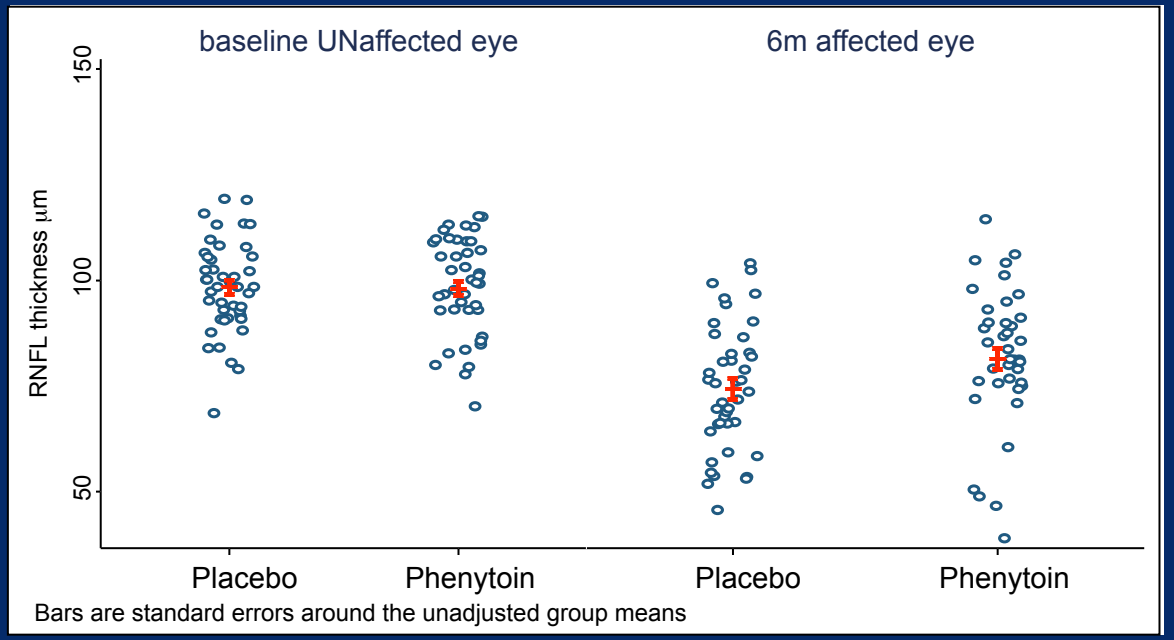
Phenytoin: trial plan

N=90, 2 centres (+UK Network)
Age 18-60 yrs
VA ≤ 20/30
Treat within 14 dy 'window'
±MS, no prior visual problems
All offered corticosteroids



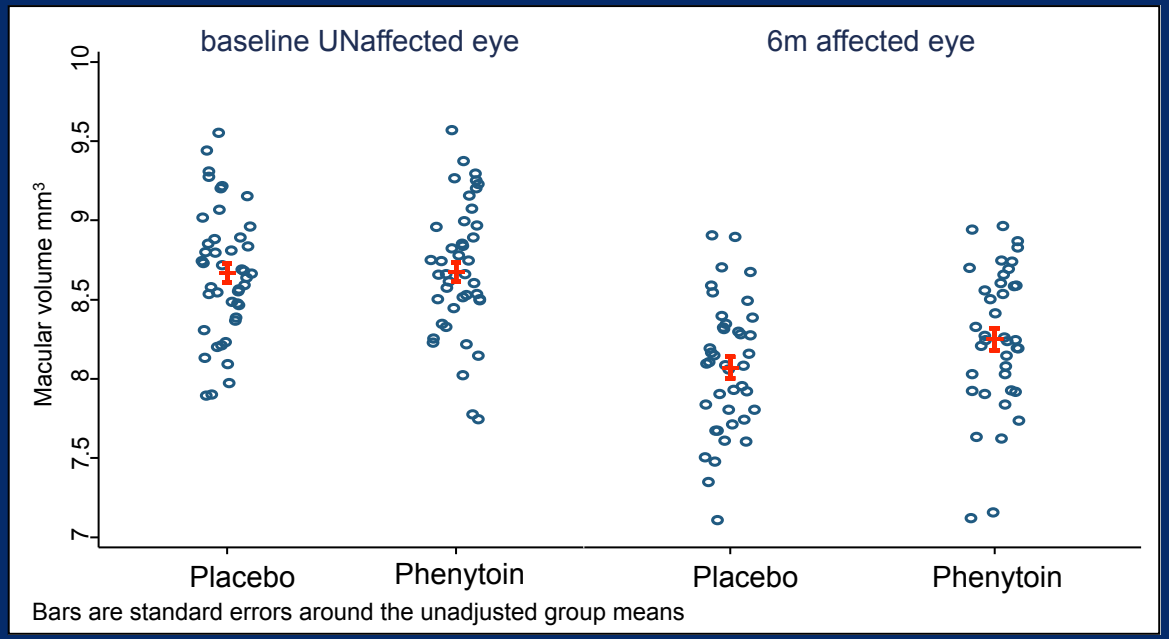
Double blind, randomised placebo-controlled, parallel group design
Initial dose 15 mg/kg, daily 4 mg/kg (max 300mg) , treatment duration 3 months
Blinded assessing and treating physicians; 2 imaging sites (Sheffield, London)
Treat beyond the inflammatory phase, delay readout to account for pseudoatrophy

Primary outcome: RNFL



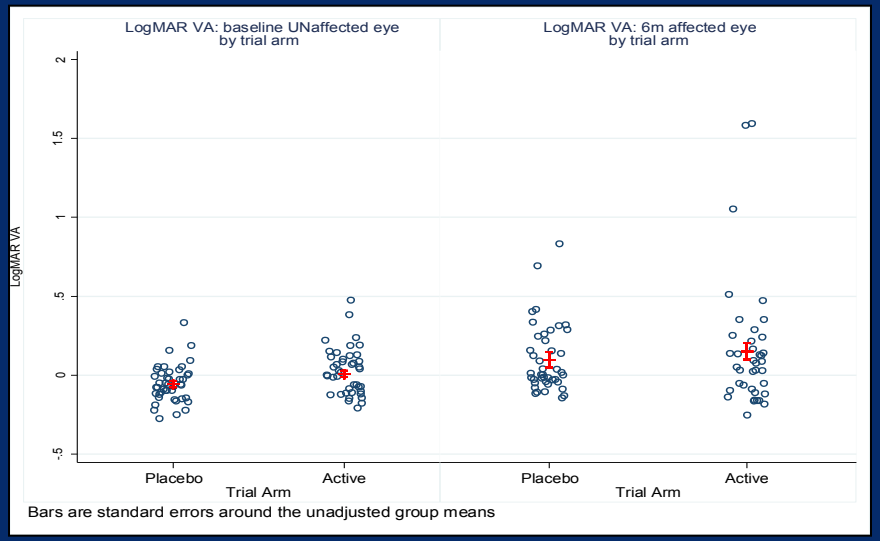
- Active-placebo adjusted difference 7.15 µm (95% CI 1.08, 13.22 p=0.02)
- 30% reduction of atrophy in active group
- PP comparison: active-placebo adjusted difference 7.40 µm (95% CI 0.76, 14.04 p=0.03)

Macular volume



- Active-placebo adjusted difference 0.20 mm^3 (p=0.005)
- 34% reduction of atrophy in active group
- PP comparison: Active-placebo adjusted difference 0.20 mm^3 p=0.01)

Visual outcomes



LogMAR

2.5% Sloan

Conclusions

- Optic neuritis presents an excellent opportunity to test acute neuroprotection in MS
- Results of recent trials support the feasibility and utility of OCT for measuring structural outcomes
- Trial designs should incorporate multiple exploratory measures, including refined biomarkers and clinical outcomes