

**Objective** To describe the design and progress of STREAMS (Stem cells in Rapidly Evolving Active Multiple Sclerosis), the first Phase 2 randomised, double-blind trial of autologous mesenchymal stem cells (MSCs) in highly active MS.

**Background** The potent immunomodulatory, neuroprotective and potentially reparative properties of MSCs are being exploited in a number of clinical trials in MS; STREAMS differs by its distinctive design.

**Methods** Recruitment of 13 patients with highly active MS. Disease 'activity' is characterized clinically by the presence of relapses or disability progression in the preceding 18 months and radiologically by the presence of a gadolinium enhancing lesion (GEL) on MRI brain within 6 months of the bone marrow harvest.

The patient receives either MSCs (standardised at  $2 \times 10^6$  cells/kg) or placebo at Week 0 with treatments reversed at Week 24. Clinical assessments, MRIs and ex-vivo immunophenotyping of peripheral blood is performed in the intervening weeks. The primary endpoints are safety and number of GELs on MRI at Weeks 4, 12 and 24.

**Results** 10 patients have been enrolled, five infused and another three are in culture. No adverse events have been recorded to date.

**Conclusion** These initial results support the safety and feasibility of mesenchymal stem cell therapy in MS.

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#### STREAMS: PRELIMINARY RESULTS FROM A PHASE II TRIAL

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