The MS-STAT2 trial in Secondary Progressive MS
Study design and update

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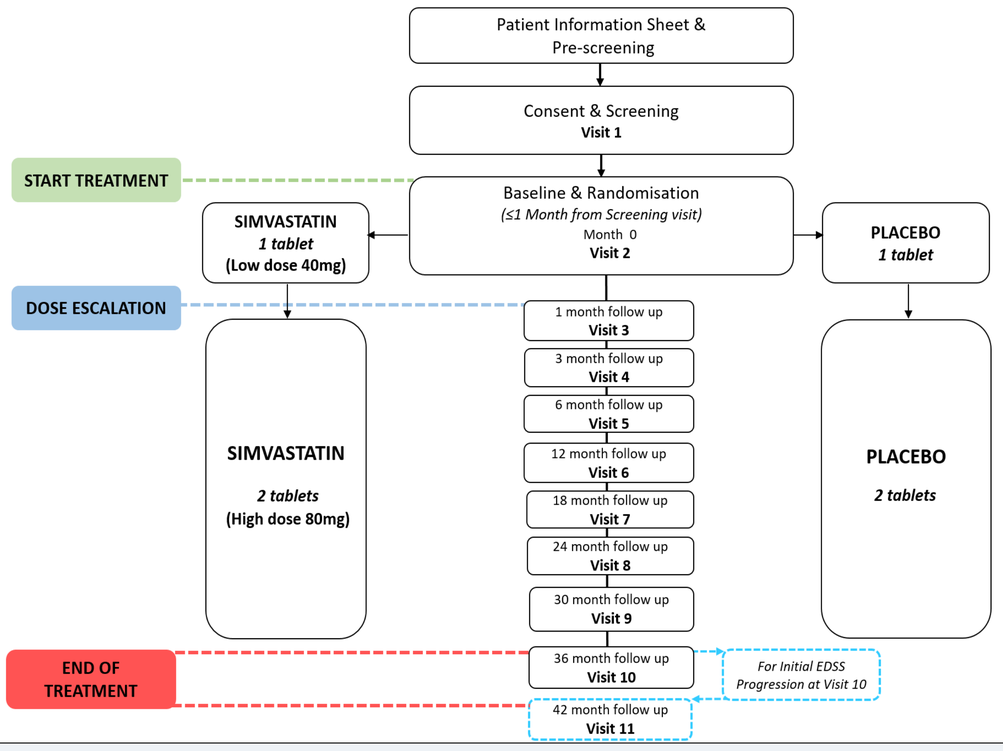
Introduction

The MS-STAT2 study is a Phase III, 3 year multi-centre, randomised, placebo-controlled trial assessing the efficacy of 80mg simvastatin vs. placebo in secondary progressive multiple sclerosis (SPMS).
Building upon the promising results of the MS-STAT1 study, it is an academically led study funded through a collaboration of the NIHR HTA, MS Society (UK), National MS Society (US), and the Rosetrees Trust

Study outline

- Recruitment target: 1180 patients, ~30 sites around the UK
- Primary outcome – time to initial disability progression on EDSS
- Secondary outcomes will include a modified Multiple Sclerosis Functional Composite (MSFC), as well as visual, cognitive and patient reported outcomes

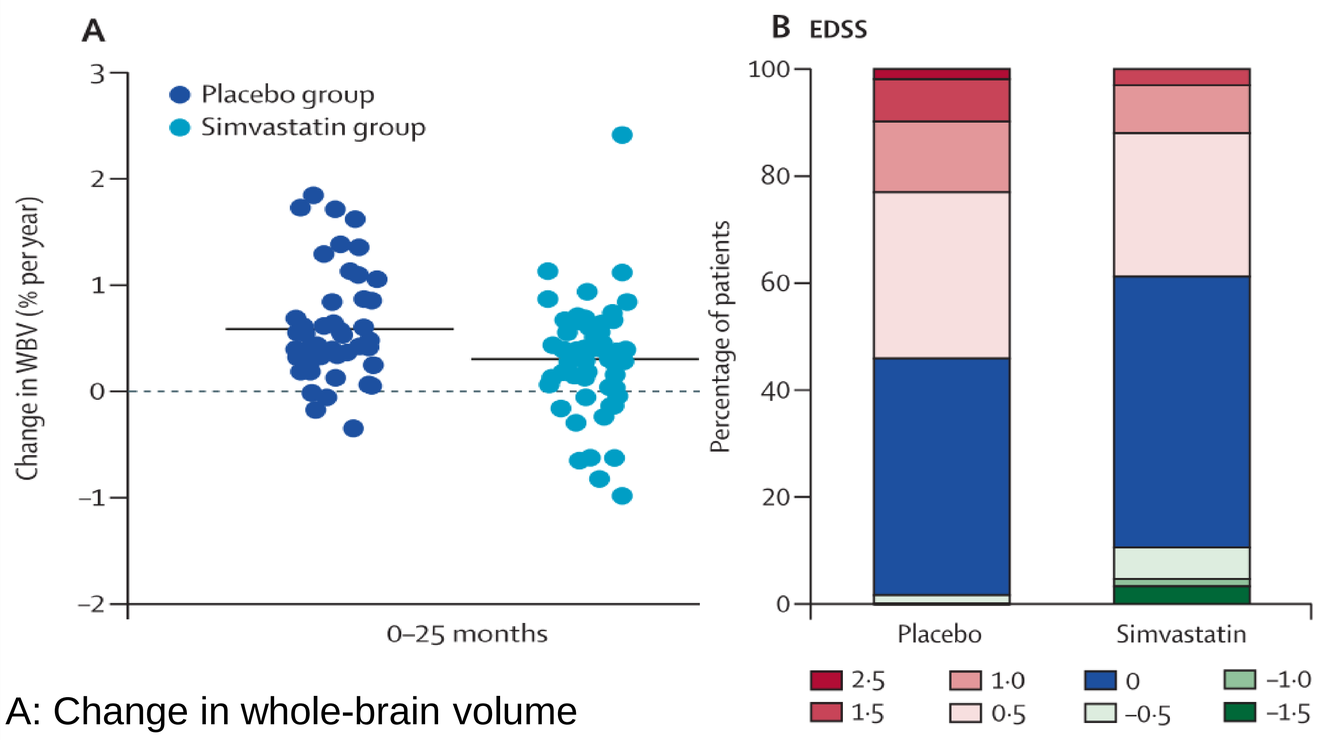
Following screening to confirm eligibility and consent, patients will be randomised 1:1 to 80mg simvastatin or placebo and embark on a total of 10 study visits over 3 years



MS-STAT1 results:

140 patients with SPMS were randomised to simvastatin or placebo:

- The 80mg simvastatin treatment was well tolerated with no difference in adverse events between groups.
- In particular, there was no difference in muscle symptoms (14% placebo, 17% simvastatin).
- Simvastatin resulted in a 43% reduction in the annualised rate of whole brain atrophy (p=0.003), in addition to reduced disability progression on EDSS (p<0.01)



A: Change in whole-brain volume
B: Change in EDSS
For both change in whole-brain volume and EDSS, a positive value indicates a worse outcome

Key messages:

- The MS-STAT2 trial is set to be a landmark study for SPMS
- Recruitment is accelerating at ~30 sites around the UK, with >1/3 of the target already recruited

Eligibility criteria:

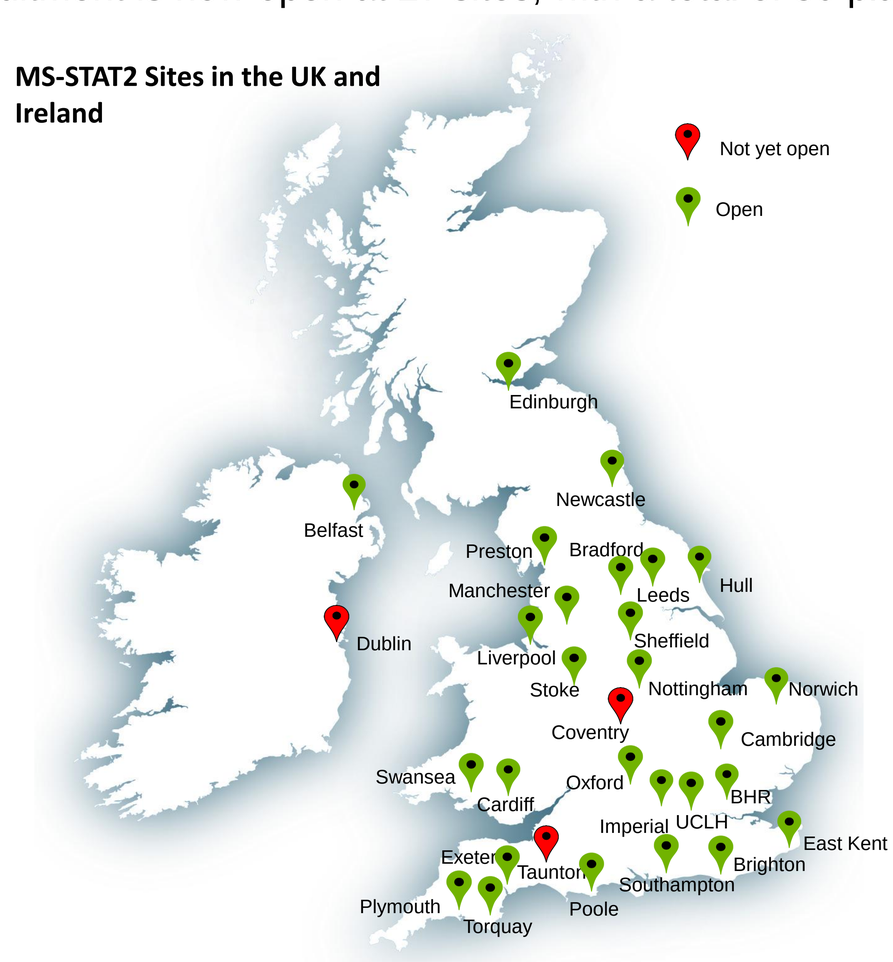
- Diagnosis of SPMS with evidence of disability progression over the last 2 years
- No current DMT use, not taking a statin
- EDSS 4.0-6.5 (patients with some disability, but still able to walk 20m, with or without walking aids)
- Age 25-65 (randomisation must occur before 66th birthday)

Contacts and patient referrals:

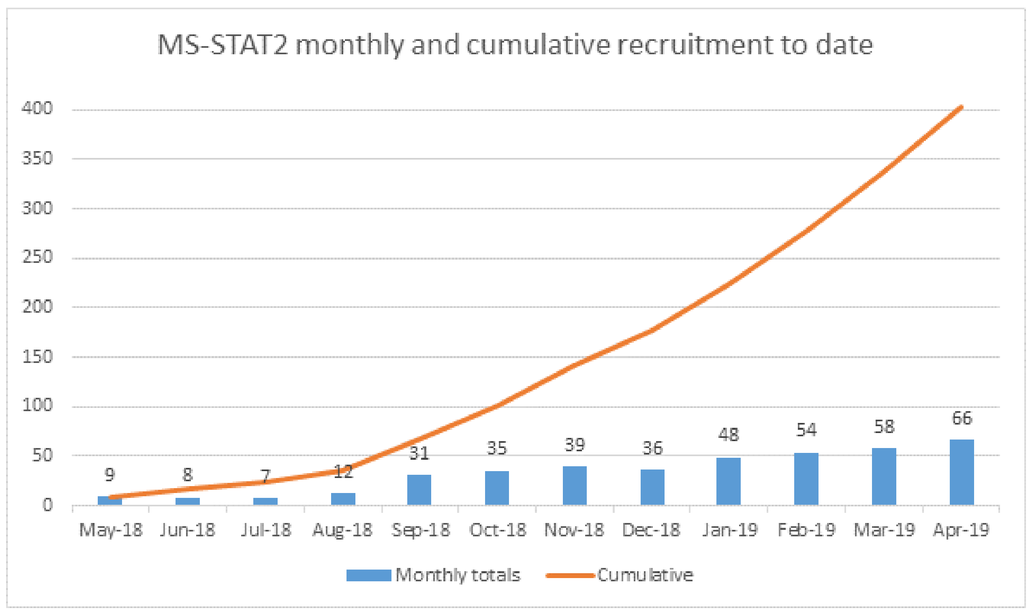
- Patients may self-refer via the registration of interest portal:
  - **www.ms-stat2.info**
- Healthcare professionals can contact the MS-STAT2 study team directly:
  - **UCLH.QSMSC@nhs.net**
- Follow us on twitter:
  - **@MsStat2**

Study sites and recruitment update:

Recruitment is now open at 27 sites, with a total of 30 planned:



Recruitment continues to accelerate, with >400 patients recruited as of May 2019:



References:
1. Chataway, J et al. *The Lancet* 383.9936 (2014): 2213-2221.
2. Chan, D et al. *The Lancet Neurology* 16.8 (2017): 591-600.
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