BRAVE DREAMS: study design of a multicenter RCT

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Purpose: to study safety and efficacy of endovascular treatment of chronic cerebrospinal venous insufficiency (CCSVI) in relapsing-remitting and secondary progressive multiple sclerosis (MS) patients.

Trial design: a multicenter, sham-controlled, parallel-group study, with imbalanced randomisation (2:1), conducted in Italy.

Eligible participants: adults aged 18-65 years with a definite MS according to the McDonald's criteria (2005) and a confirmed diagnosis of CCSVI according to the criteria of the International Union of Phlebology (IUP 2009) and based on a defined ECD investigation protocol.

Setting: MS Centers of the National Health System

Interventions: selective venography (SV) and percutaneous transluminal angioplasty (PTA) *vs.* SV and sham PTA.

Primary outcomes with respect to efficacy in MS: (i) the proportion of improved patients from baseline to 12 months as measured by a clinical composite endpoint; (ii) the number of active MRI lesions at 12 months.

Sample size: 650 patients to be recruited in 12 months.

Blinding: patients, neurologists, outcome assessors and statisticians will be kept blinded to the allocation.

Follow-up: 12 months.