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Feedback from Scientific Committee regarding Zamboni PI trial proposal

The Scientific Committee was briefed by an internal member and by the FISM president about the history of development of the proposal and reviewed the clinical trial protocol. The SC was favorably impressed by the carefully written study protocol. However, the SC felt that a randomized, sham-controlled clinical trial in a large number of subjects would be premature until stronger evidence of a causative association of CCSVI to MS, or stronger evidence of a treatment effect of venoplasty (such as can be provided by a carefully conducted, proof-of-principle controlled clinical trial in 20-30 subjects) are available.

The main points underlying this criticism were:

- Diagnostic phlebography and venoplasty are invasive procedures with non-negligible radiation exposure and risks of adverse events
- Scientific methodology in clinical research is organized in specific phases in the interest of patient safety and optimal utilization of resources. Under universally accepted paradigms, clinical trials proceed from Phase 1 studies (to establish safety of a diagnostic or treatment intervention in a small number of subjects generally in healthy volunteers), to Phase 2 trials (to establish safety and obtain preliminary evidence of efficacy in a relatively small number of patients affected by the condition treated), to Phase 3 trials to definitely establish efficacy in large numbers of patients and provide data to apply for licensing. The SC unanimously agreed that in light of safety concerns, there is a need for high-quality phase 2 data before further experimentation in a large number of patients such as those envisioned in the proposed trial protocol can be funded by FISM.

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