

## Treatment of Brain AVMs (TOBAS)

TOBAS is a pragmatic, prospective, multicenter, randomized, controlled trial and registry which offers a care trial context for brain AVM patients, including surgical resection, radiosurgery or endovascular embolization, alone or combined. The study includes two RCTs and a multimodality prospective registry. The objectives of the proposed study are to assess whether preventive interventions (surgery, embolization, radiation therapy, alone or combined), selected by the local treatment team and performed as locally practiced, randomly allocated and compared with conservative management, in unruptured brain AVM patients eligible for active or conservative management, can improve the proportion of patients having an independent outcome (modified Rankin Scale (mRS) < 3, as assessed by a standardized questionnaire administered by non-masked care personnel) at 10 years. All patients judged ineligible for randomized allocation are to be entered in a multimodal registry. The objective of a nested trial in patients with ruptured or unruptured AVMs to be treated by surgery or radiation therapy, is to assess whether pre-surgical or pre-radiation embolization, randomly allocated and compared with no embolization, can improve the proportion of patients with complete eradication of the AVM, as locally adjudicated, combined with a good clinical outcome (mRS < 3). The study will require up to 2000 patients in approximately 30 centers or more, followed for 10 years. TOBAS is registered at [clinicaltrials.gov](https://clinicaltrials.gov): NCT02098252 as of 25 March 2014 <sup>1)</sup>.

The TOBAS study consists of two components: one is a register and the other one is a randomised trial. While we obviously agree that randomisation is the best way to achieve scientifically pure data, we see the many difficulties and limitations of such an approach, not least the loss of the data coming from all the cases excluded from the study (200 included and 1,700 excluded in the Aruba study) <sup>2)</sup>.

<sup>1)</sup>

Darsaut TE, Magro E, Gentric JC, Batista AL, Chaalala C, Roberge D, Bojanowski MW, Weill A, Roy D, Raymond J. Treatment of Brain AVMs (TOBAS): study protocol for a pragmatic randomized controlled trial. *Trials*. 2015 Nov 4;16:497. doi: 10.1186/s13063-015-1019-0. PubMed PMID: 26530856; PubMed Central PMCID: PMC4632683.

<sup>2)</sup>

Cenzato M, Boccardi E. RCT vs register. *Acta Neurochir (Wien)*. 2017 Aug 8. doi: 10.1007/s00701-017-3279-9. [Epub ahead of print] PubMed PMID: 28791430.

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