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TOBAS (Treatment of Brain AVMs): A randomized controlled trial and registry

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Introduction

While treatment of ruptured AVMs are rarely questioned, the management of unruptured AVMs remains controversial. The ARUBA trial *(1)* suggested that medical management is superior than intervention in patients with unruptured AVM. The study was critical in many respects and it is that difficult to anticipate the future position of care teams: full stop interventionist treatment or continuing the usual practice. These two attitudes seem innapropriate. More trials are needed.

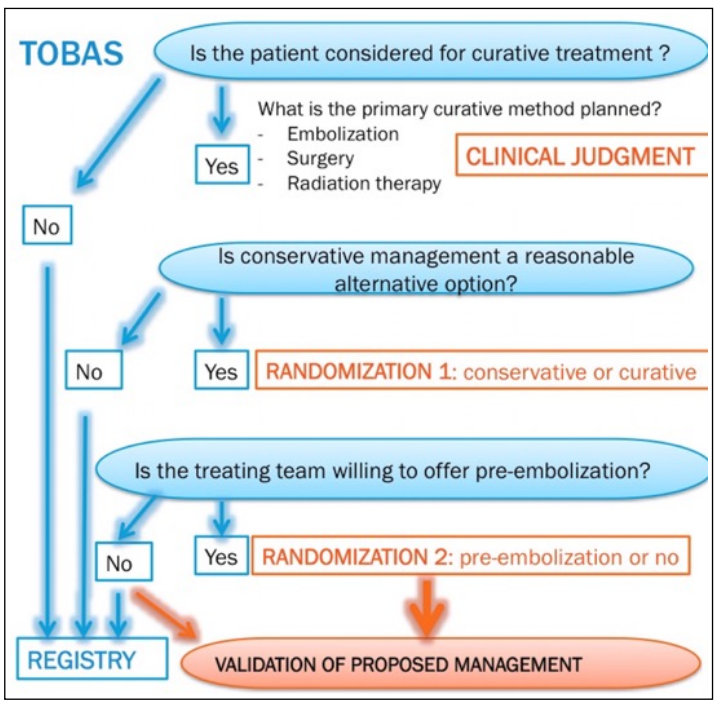
The aim of a new trial is to provide a care trial context *(2)* to offer yet-to-be validated curative treatments to brain AVM patients.

Methods

TOBAS is a pragmatic, prospective, randomized controlled trial and registry, intends to include all AVM patients.

- Patients will be randomly allocated conservative or curative treatment, when eligible to both options.
- The curative treatment modality (embolisation, surgery, or radiosurgery) will be predetermined prior to a stratified randomization based on clinical judgement.
- All patients managed according to clinical judgement alone will be included in the registry.
- Randomization will be stratified by treatment modality and minimized according to a history of previous rupture and Spetzler-Martin grade (3).
- The primary outcome of the study is death (any cause) or disabling stroke (mRS >2) at 10 years.
- In addition, a nested RCT within TOBAS will examine the role of embolization prior to surgery or radiosurgery, when these can be performed with or without embolization, hoping to increase the proportion of complete AVM eradication without a disabling complication.

	ARUBA	TOBAS
Experiment	Medical management	Interventions (Stratified)
Primary Hypothesis	In favor of medical	In favor of interventions
Primary outcome	Time to any stroke or death	mRS>2 at 10 years
Secondary endpoint	mRS>1	Permanent deficit
Follow-up	Follow up 33 months	Follow up 10 years
Design	Pragmatic	Same



The TOBAS study is registered: ClinicalTrials.gov ID:NCT02098252.

Results

- The recruitment of 540 patients is needed to show that a treatment can reduce the primary outcome by 10% (from 25 to 15%).
- For the nested study on embolization, we estimate that 440 patients are needed to detect a 10% increase in the rate of success (from 80 to 90%).
- Currently 40 patients have been recruited in a single canadian center in less than a year.

Conclusions

In the presence of uncertainty, TOBAS may offer optimal care to patients with brain AVMs.

We are actively seeking participation of additional centers.

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References

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