ARUBA – A RANDOMIZED TRIAL OF UNRUPTURED BRAIN AVMS

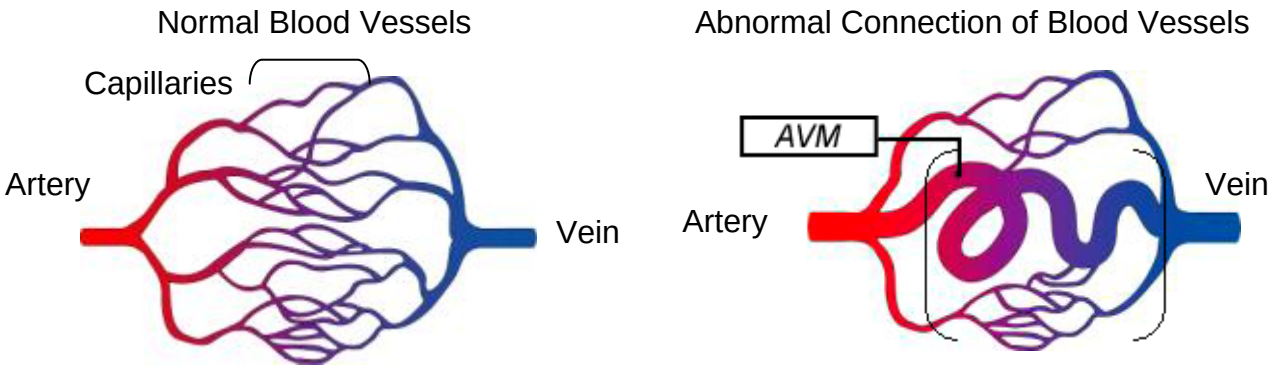
Information for interested patients, their friends and families

The ARUBA study is a clinical trial to find out better ways of caring for people, who have been discovered to have an arteriovenous malformation (AVM) in the brain that has never bled.

If you are an AVM patient, the information provided on this website may help you decide if you want to participate in the trial. We will also provide contact information about participating doctors and hospital centers in North and South America, Europe, and Australia.

WHAT ARE AVMs?

Brain AVMs are a tangle of arteries and veins which represent errors in vessel formation thought to date back to birth. The arteries bring blood from the heart link directly to the vein draining blood back to the heart without the normal tiny vessels called capillaries which allow regular blood flow and slow it enough for oxygen and blood sugars (glucose) to provide the brain with nutrition. So, instead of supplying blood to the brain tissue itself, AVMs shunt (divert) blood through their abnormal channels back to the veins leading back to the heart.



WHAT IS A CLINICAL TRIAL LIKE "ARUBA"?

Clinical trials are different from the usual care provided by doctors. It is a method of testing which of several different approaches to your problem can give the best long-term results.
In ARUBA, we want to learn if it is better to leave the AVM alone, since it has never bled, and treat only the symptoms (like headache or seizures), or to undertake efforts to eliminate the AVM using one or more of several available techniques. Information available to doctors world-wide is not enough to decide which approach is best.

DO I HAVE TO TAKE PART IN THIS TRIAL?

No! It is up to you if you take part or not, and all participation is voluntary. You may want to share with your family, friends, family doctor, or other doctors before you make up your mind whether to join. If you do decide to take part, you can still change your mind and stop participating at any time.

WHY IS THIS TRIAL BEING DONE?

A brain AVM could bleed injuring adjacent brain tissue and causing a stroke. Treatment o eradicate the AVM can also injure the brain during deliberate blocking of the flow of blood in arteries to the AVM (a process called embolization), during surgery to remove the AVM, or after radiation therapy designed to obliterate the AVM. The available evidence does not clearly indicate which approach will offer the best long-term favorable results. This is why doctors around the world think it is best to manage unruptured AVMs within a systematic study.

HOW IS THE STUDY DONE, FOR HOW MANY AND FOR HOW LONG?

To answer the question which is best (i.e., medical management alone or treatment to eradicate the AVM), the two approaches can only be judged by dividing the patients eligible for the trial into the two groups as evenly as possible. The process of dividing the two groups is known as randomization (like the flip of a coin).

You will be on study for 5 years to 7.5 years from today, depending on how long it takes to enroll enough patients worldwide to answer the question “which is better”. During this time, you will be personally followed by a dedicated team of doctors at least every 6 months until the end of the study.

800 patients are planned from close to 100 different institutions in North America, Europe, Australia and South America.

ARE THERE RISKS TO THE STUDY?

There are risks in any study, but in ARUBA the risks are the same as they would be if you and your doctors decided on any of the treatments being tested without participating in the trial.

ARE THERE ANY SECONDARY FINANCIAL INTERESTS IN THE STUDY?

No! ARUBA is entirely sponsored through public funds provided by the US National Institutes of Health. Neither doctors nor patients will receive any personal refunds for participating in the study. Also, ARUBA has been designed by specialists interested in improving management of patients with unruptured AVMs, and there is no direct or indirect involvement of any industry or insurance carriers.

The protocol is officially registered at a variety of international organisms promoting transparence of clinical research projects, including the “International Standard Randomised Controlled Trial Number Register” (http://www.controlled-trials.com/ISRCTN44013133) and the “ClinicalTrials.gov” registry (http://clinicaltrials.gov/show/NCT00389181).

WHAT IF I AM INTERESTED IN PARTICIPATING? WHO MAY I CONTACT FOR ADDITIONAL INFORMATION?

The following links will guide you to participating hospitals in many parts of the world. Doctors involved are among the best specialists in the field and will be happy to discuss any further details with you.

United States	[hyperlink to list of US sites by state]
Canada	[hyperlink to list of Canadian sites]
Europe	[hyperlink to list of European sites by country]
Australia	[hyperlink to list of Australian sites]
South America.	[hyperlink to list of South American sites by country]

For any additional questions, you may also send an email to one of the international study coordinators:

If you live in North or South America, or Australia:

J.P. Mohr, MD New York, NY
Email: jpm10@columbia.edu

If you live in a European country:

Christian Stapf, MD Paris, France
Email : christian.stapf@lrb.aphp.fr