

You are invited to participate in TEAM because, in your case, your physician believes that it is possible to treat your aneurysm using the endovascular approach with reasonable risks. However, your physician also believes that it is equally reasonable not to treat the aneurysm, because the risks of rupture may be as low as the risks of treatment.

TEAM compares between two groups.
You will belong to one of the two following groups :

Observation group or **Treatment group**

Every participant will have an equal chance to belong to any of the two groups. Nobody will know, beforehand, to which group you will be assigned, not even the physician or his assistant. This procedure is known as randomization, and it enables limiting the amount of bias. Bias is a prejudice, a preconceived judgment, or an unfounded belief on the part of the physician. Limiting bias through randomisation is an important prerequisite to acquire scientifically valid knowledge

All along the study, researchers will compare both groups to know if differences arise. If we get to know which treatment is best, the study will be over and you will be immediately informed.

What is an aneurysm ?

An aneurysm is an anomalous sac-like dilatation arising from the wall of the arteries, and associated with a weakness in the arterial wall.



For any questions pertaining to your rights,
you may contact :

TEAM is approved and funded by the
Canadian Institutes of Health Research.

TEAM is registered in the International
Standard Randomised Controlled Trial
Number Registry ISRCTN62758344
<http://www.controlled-trials.com>

www.TEAMstudy.org

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participate in **TEAM**

Reflexion Guide

What are the possible treatments ?

There are 3 treatment options for an unruptured aneurysm:

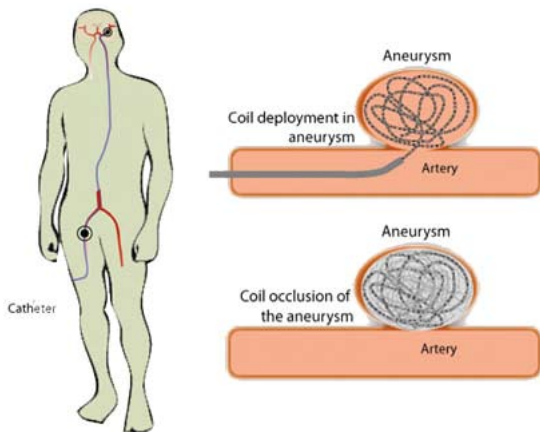
Conservative treatment, whereby the principle is not to approach the aneurysm in order not to submit the patient to any immediate treatment-related risks, whether surgical or endovascular

Endovascular treatment

Surgical treatment

What does endovascular treatment consist of ?

A small incision is performed in the artery of the groin under general anesthesia, and a catheter is introduced and guided through the arteries to reach the cerebral vessels. Platinum wires (the coils) are deposited in the aneurysm. Since these coils are flexible, they will adopt the shape of the aneurysm. The aneurysm is thus embolised (occluded) to exclude it from the cerebral circulation.



The intervention lasts on average 2 hours. Although it can vary from one hospital to another, the hospital stay can be 1-3 days. Generally, you will be able to resume your activities immediately or, at the most, after a few days.

What are the steps if I decide to participate ?

1st visit (today):

Your physician will explain the study, its goals and why he thinks you should participate. He will hand out an information leaflet and will ask you to think thoroughly about it. He will see you again following a delay of between 2 days to 2 weeks. During this

reflexion period, you may call the TEAM staff at any time if you have questions.

2nd visit:

Your physician will ask you if you have made up your mind. If you do not want to participate in the study, in no way will your relationship with your physician change. If you wish to participate in the study, we will proceed with “randomization”, that is, you will be assigned to either one of the two groups. A research assistant will help you in filling out 3 simple questionnaires including questions related to your emotions and your level of anxiety (please plan for a minimum of 30-45 minutes for this visit).

If you are assigned to the “Observation” group:

Your physician will inquire about you in one month. This may be done by phone or in his office. He will ask you simple questions about your health.

If you are assigned to the “Treatment” group:

Your physician will set an appointment for endovascular treatment. The procedure will take place within 1-2 months of the second visit.

In both cases:

At 6 months, you will see your physician again. You will be proposed a radiological exam. At 1 year, you will see your physician and you will have to fill out the questionnaires on your health status. You will thus be followed every year for 10 years.

Benefits:

You will be followed very closely. You play an active role in the maintenance of your health. You have the opportunity to contribute to the advancement of medical knowledge.

Risks:

Endovascular treatment entails known risks. Complications arise in not more than 10% of cases, but often have no repercussions. Nevertheless, consequences may be severe in 2 to 4% of cases.

Conservative treatment (observation) has the advantage of not submitting the patient to the risks of treatment. The risk of rupture, however, remains present; it is a low risk, estimated at 0.5 to 2% per year.

You may ask questions :

Please take the time to inquire about all aspects that you do not understand or which are not clear, and talk about what is important to you.

You may change your mind and leave TEAM at any time :

Participation in TEAM is entirely voluntary. In case you choose to participate, you may withdraw from the study at any time without having to justify yourself, and without it affecting your relationship with your physician or the treating staff.

You have rights. They shall be protected.

Many expert panels, international as well as local, have approved TEAM before the start of the study. One of those panels is the Institutional Ethics Committee.

Remember:

By accepting to participate in TEAM, you partake in the development of medicine. You actively contribute to the transformation of knowledge, while, at the same time, being guaranteed a very close follow-up.

The decision to join the study is yours!

We believe that for you, this is the best choice. Speak about it to your family, your friends and your physician. Yet, the decision belongs to you.

But the decision is yours.

