

ATHN 2

A Study on the Effects of Switching Factor Products



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Are you thinking
about switching
to a new factor
product?

If so, consider
being part of the
ATHN 2 factor
switching study.

“ATHN 2 will provide important information to the entire hemophilia community over the next few years, especially about switching in patients who previously had inhibitors who were excluded from pivotal clinical trials.”

Dr. Ellis Neufeld, Principal Investigator, Clinical Director,
Physician-in-Chief and Executive Vice President, St. Jude
Children's Research Hospital

With more than 10 new factor replacement products for hemophilia A or B becoming available, many patients like you are likely to switch to a new product over the next few years. To better understand the effects of switching to any of these new factor products, the American Thrombosis and Hemostasis Network (ATHN) is sponsoring a new research study: *ATHN 2 – A Longitudinal, Observational Study of Previously Treated Hemophilia Patients (PTPs) Switching Factor Replacement Products.*

What is the goal of the ATHN 2 factor switching study?

ATHN 2 will assess whether patients who have received factor replacement in the past will develop inhibitors after switching to a new factor product. Because inhibitors are most likely to appear within the first 50 days of factor use,¹ the likelihood that previously treated patients will develop new inhibitors is small but needs to be better understood.

How is this factor switching study different from other studies?

As you may know, developing an inhibitor is a potentially serious complication of hemophilia. An inhibitor is like an antibody that makes the factor less effective or not work at all. ATHN 2 is important because it will study patients who have been treated in the past for at least 50 days with recombinant or plasma-derived factor products. Unlike clinical trials of individual factor products, it is designed to study all of these new factor products over many years, after they have been FDA approved. And patients who have a prior history of inhibitors to factors (but are free of an inhibitor now) are eligible to participate.

This vital research will help determine whether switching factors may be related to the development of new inhibitors in patients who have received treatment in the past—and ultimately could help us learn more about how to prevent inhibitors in the future.

¹ Ragni, MV, Kessler, CM, and Lozier, JN (2009). Clinical aspects and therapy for hemophilia, in Hoffman R, Benz EJ, Shattil, SJ et al., eds, Hematology, Basic Principles and Practice, 5th Edition, Churchill Livingstone, Philadelphia, pp 1911-1930.

Where is ATHN 2 being conducted?

ATHN 2 is a multi-center study being conducted at hemophilia treatment centers (HTCs) like the one where you receive care. Approximately 20 to 30 HTCs are working with ATHN to run the study over a 6-year period. You will be followed for up to 1 year after you switch to a new factor, and potentially for multiple years if you switch factors again.

Who is eligible?

You and/or your child may be eligible to participate in the study if you:

- Switched to a new factor product within the past year
- Are planning to switch to any of the new factor products

How you can get involved

If you are interested in participating in ATHN 2, talk to your HTC provider about the study. A member of the study team will go over all the details with you and obtain your consent to participate. This study involves:

- Planned study visits
- 1 blood draw after 10 days of factor use
- A phone call every 3 months
- Additional visits (if you develop new symptoms)

As part of your routine care, you will be monitored for any signs of inhibitor development. It is important to note that your participation is voluntary and will not affect the quality or timing of care that you and/or your child receive at this HTC. You are free to leave the study at any time.

Talk to your HTC provider about ATHN 2 today!

ATHN 2

Ask your HTC about ATHN 2 today!
Your participation in the ATHN 2
factor switching study could help
researchers better understand why
inhibitors develop, an essential
next step toward improving
treatment.

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**To learn more, go to clinicaltrials.gov
(keyword "Factor") or ATHN.org/ATHN2.**



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