PROGRESS IV CLINICAL TRIAL FAQ FOR PATIENTS

PROGRESS IV
CLINICAL TRIAL

1. What is the PROGRESS IV clinical trial?

The PROGRESS IV clinical trial is investigating a device called the nSTRIDE® APS Kit for people who have osteoarthritis (OA) in one knee. Osteoarthritis, the most common type of arthritis, is a progressive disease of the joints.[i, ii] Often referred to as "wear and tear" arthritis, OA occurs when the top layer of cartilage, the slippery tissue that covers the ends of bones in a joint and helps absorb the shock of movement, breaks down and wears away.[iii]

2. What is the goal of the PROGRESS IV clinical trial?

The goal of the PROGRESS IV clinical trial is to evaluate the safety and clinical effectiveness of a protein solution prepared from a small sample of your own blood with an investigational device called the nSTRIDE APS Kit, on pain and function associated with knee osteoarthritis.

3. What does APS stand for?

APS stands for autologous protein solution. An autologous solution is one for which the donor and recipient are the same person. The autologous protein solution being prepared with the nSTRIDE APS Kit for the PROGRESS IV clinical trial is a concentrated solution of proteins prepared from a small sample of your own blood.

4. How much blood will need to be drawn, from where, and how often?

A small amount of blood - approximately 120 milliliters (8 tablespoons) - will be drawn from your arm, one time.

5. What is saline?

Saline is a salt water solution. Results of saline-injected patients will be compared to results of APS-injected patients.

6. What are the procedural steps for the PROGRESS IV clinical trial?

The procedure involves the following steps:

- You will complete extensive, non-invasive screening testing
- You must not take pain-relieving medicines 48 hours before each trial visit, nor pain-relieving medicines except acetaminophen during the entire trial
- A small amount of blood - approximately 120 milliliters (8 tablespoons) – is drawn from your arm
- Your blood sample is processed in its own nSTRIDE APS device to separate the different parts of the blood
- The resulting protein solution will be removed and placed into a syringe
- The solution (or saline) will be injected into your knee. You will not know which injection you received.

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7. What kind of care and follow up will I receive as part of the PROGRESS IV clinical trial?

Follow-up visits will occur over one year. The schedule of visits is as follows:

- Screening visit (includes an X-Ray and MRI)
- Injection visit (within 28 days of screening)
- Follow-up visit one month after injection
- Follow-up visit three months after injection
- Follow-up visit six months after injection
- Follow-up visit 12 months after injection (includes an X-Ray and MRI to assess anatomical changes)

After the 12 month visit, patients may choose to receive an injection of APS. If you do choose to receive another injection, you will have two additional visits:

- Second injection visit
- Second injection follow-up visit one month after second injection

8. How will I know if the injection is working or not?

The trial is designed in a way that doesn't allow you to know if you are receiving an injection of saline or the experimental APS. Once the trial period is over, your physician will be able to tell you if you received saline or APS, and together you can discuss any clinical benefits you may have achieved.

9. What is the chance I will receive APS?

There is a 50 percent chance that you will receive APS. However, upon completion of all follow-up evaluations, no matter which injection you received, you will have an opportunity to enter a one month open-label APS trial phase if you had no major safety concerns due to the first injection.

10. What are the potential risks involved with participating in the PROGRESS IV clinical trial?

Potential risks involved with participating in the PROGRESS IV clinical trial may include side effects such as bruising, local pain or swelling associated with the blood draw, joint fluid aspiration or knee injection. Other possible risks include infection at the injection site, fainting, scar tissue formation or nerve/nervous system damage. There are risks associated with MRI and X-Ray procedures, such as exposure to radiation and anxiety. Your osteoarthritis may not improve or may get worse. Your doctor will discuss all the possible risks with you before you choose to participate in the trial.

11. What are the potential benefits of participating in the PROGRESS IV clinical trial?

Potential benefits may include relief of pain and better knee function, as well as structural improvement within the joint. After completing the 12-month follow-up assessments, you will be eligible to receive an additional injection of the investigational APS.

12. How long will the PROGRESS IV clinical trial take?

Your participation in the trial will last approximately 16 months, with at least 6 doctor's office visits.

13. Where are the trial sites?

The clinical trial sites for the PROGRESS IV clinical trial include some of the most highly respected medical institutions in the country, experienced in treating this condition. Visit **www.zimmerbiomet.com/nstridetrial** for a full list of clinical trial sites.

14. What would make me a candidate for the PROGRESS IV clinical trial?

Some of the criteria you must meet to be in the trial are listed below. If you do not meet all of these, you will not be able to participate. If you meet all of these criteria, your doctor will then determine if you meet the remaining criteria and can be enrolled in the trial. You must meet the minimum requirements:

- Have symptomatic osteoarthritis in only one knee
- Be between 21 and 80 years old at time of injection
- Be willing and able to comply with the trial procedures and visit schedules
- Have a body mass index less than or equal to 40 kg/m^2
- Have undergone at least one conservative osteoarthritis treatment without satisfactory pain relief
- Not have had recent intra-articular steroid injections (3 months) or hyaluronic acid (HA) or other joint injections (6 months) in the arthritic knee

> **To see if you qualify for the PROGRESS IV clinical trial, visit zimmerbiomet.com/nstridetrial, text 1KNEE to 87888 or call 773-313-3077.**

15. How do I register for the PROGRESS IV clinical trial?

Visit **www.zimmerbiomet.com/nstridetrial** to identify a clinical trial site and trial coordinator. Once you have identified a clinical trial site, you can contact the site coordinator directly to begin the screening process.

16. Am I enrolled automatically once I contact the clinical trial site?

No, once you contact the clinical trial site, you will have to undergo a thorough screening process to confirm if you qualify for the trial. If so, you will be asked to begin the 16-month commitment in the trial.

17. Do I need health insurance to participate in this trial?

No, you do not need health insurance to participate in this trial. If you qualify and enroll in the clinical trial, the sponsor will cover all medical costs associated with the trial including the screening, the procedure and post-procedure follow up. If, however, you need medical care beyond what this trial provides, these charges will be billed to you or your insurance company.

18. Will I be reimbursed for my participation in the PROGRESS IV clinical trial and any travel costs to get to the trial site?

You will not incur any extra costs for the medical care and examinations that are not considered standard of care. You may incur costs associated with travel to your doctor's office. Extra visits to your doctor's office are required for follow up care throughout the trial. You will receive payment for your participation in the trial. You can ask your local site coordinator for details.

19. What is an informed consent form? Who can address my questions about it, if I have any?

The informed consent is a form you must sign before enrolling in the clinical trial. Prior to enrollment, a healthcare professional from the trial site, likely the trial investigator or trial coordinator, will review the form with you and outline the clinical trial process and your role in it, the likelihood that you will receive the investigational APS or a saline injection, and all risks associated with participating in the trial. If you have any questions, you can ask the trial investigator or trial coordinator.

20. Can I leave the PROGRESS IV clinical trial at any time?

You should not enroll in the trial unless you are willing and able to honor the time commitment of the trial, including a minimum of six in-person office visits over the course of up to 16 months. However, you may choose to withdraw from the trial at any time.

21. How will my progress be monitored once the PROGRESS IV clinical trial is complete?

During the PROGRESS IV clinical trial, you will remain under your primary physician's care for all medical conditions not related to OA of the knee. No matter which group you were assigned to at the beginning of the trial (saline or APS), you will have an opportunity to receive the investigational APS if you complete all follow-up visits and had no major safety concerns due to the first injection. After receiving the second injection, you will be asked to return to the office for a follow-up visit one month later, and that visit will mark your completion of the trial. Following the trial, you will be asked to continue seeing your primary physician to monitor all health related questions and concerns, as they arise.

22. Will results of the PROGRESS IV clinical trial be provided to me?

Once the trial is complete, it will take time for the trial sponsors at Zimmer Biomet to compile the results. When the results are complete, they are typically published for public knowledge and posted on clinicaltrials.gov. Your **individual** results, however, will not be provided to you or made public.

REFERENCES

i OrthInfo. 2007. American Academy of Orthopaedic Surgeons; [accessed 2016 April 25]. http://orthoinfo.aaos.org/topic.cfm?topic=a00227.

ii Osteoarthritis (OA). 2015. Centers for Disease Control and Prevention; [accessed 2016 April 25]. http://www.cdc.gov/arthritis/basics/osteoarthritis.htm.

iii What Is Osteoarthritis? Fast Facts: An Easy-to-Read Series of Publications for the Public. 2014. National Institutes of Health; [accessed 2016 April 25]. http://www.niams.nih.gov/health_info/Osteoarthritis/osteoarthritis_ff.asp.

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