PROGRESS IV CLINICAL TRIAL FACT SHEET

PROGRESS IV
CLINICAL TRIAL

TRIAL PURPOSE

Sponsored by Zimmer Biomet, the PROGRESS IV clinical trial will evaluate the safety and clinical effectiveness of autologous protein solution (APS), prepared from a small sample of a patient's own blood with an investigational device called the nSTRIDE® APS Kit, on pain and function associated with knee osteoarthritis (OA).

nSTRIDE APS KIT

The nSTRIDE APS Kit concentrates certain anti-inflammatory components and growth factors in whole blood. The device consists of two parts: the nSTRIDE Cell Separator and the nSTRIDE Concentrator. The nSTRIDE Cell Separator utilizes centrifugal force to process the patient's blood sample, separating out the different parts. The resulting cell suspension is then put into the nSTRIDE Concentrator, which uses centrifugal filtration through polyacrylamide beads to concentrate the injectable output.

TRIAL DESIGN

The PROGRESS IV clinical trial will randomly assign patients to receive either a single injection of autologous protein solution **OR** saline. To participate in the trial, patients must have early to moderate symptomatic OA in one knee and have failed at least one prior conservative OA therapy.

Participation will require at least six doctor's office visits over a maximum period of 16 months. 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

Patients should not enroll in the trial unless they are willing and able to honor the time commitment outlined above.

CANDIDATE CRITERIA

Criteria for trial inclusion include, but are not limited to:

- Symptomatic osteoarthritis in only one knee
- Between 21 and 80 years old
- Willing and able to comply with the trial procedures and visit schedules
- A body mass index less than or equal to 40 kg/m^2
- At least one prior conservative OA 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

For trial protocol summary, additional inclusion and exclusion criteria, and a list of all trial site locations, please visit: www.zimmerbiomet.com/nstridetrial

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