Figure 1

Figure 2

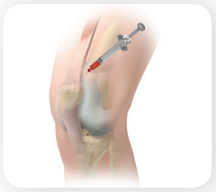

Figure 3

Procedure

- You will complete extensive, non-invasive screening testing
- You must not take any 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) – will be drawn from your arm, one time
- Your blood sample will be processed in its own nSTRIDE APS device to separate the different parts of the blood (Fig. 1)
- The resulting protein solution will be removed and placed into a syringe (Fig. 2)
- The solution (OR saline) will be injected into your knee. You will not know which injection you received until after the trial. (Fig. 3)

Care and Follow Up

You should minimize physical activity for 14 days after injection (to not exceed the pre-injection level of activity).

You will be examined and will complete questionnaires at the doctor's office at 1,3, 6, and 12 months after your injection.

At your 12 month visit, you may choose to receive an injection of APS.

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PROGRESS IV
CLINICAL TRIAL

Patient Education Brochure

nSTRIDE® APS Kit
Clinical Trial for Knee Osteoarthritis

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Caution: Investigational device, limited by federal (or United States) law to investigational use.

This trial will evaluate the safety and clinical effectiveness of autologous protein solution (APS), 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 (OA). In this study, nSTRIDE APS will be compared to a saline injection. Half of the study participants will receive an APS injection and half will receive a saline injection. You will not know which injection you received until the end of the study.

If you are comfortable with the procedure and information outlined in this brochure and meet all the requirements on the following page, you may be eligible to participate in an approved clinical trial for osteoarthritis of the knee.

Benefits of Taking Part in the Trial

You may or may not benefit from taking part in this trial. The possible benefits you may have from being in this trial include the relief of osteoarthritis symptoms in your knee, including pain relief, knee function restoration and anatomical improvement within the joint. Information learned in this trial may help patients with osteoarthritis in the future.

Potential Risks

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.

Costs

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 participation in the trial. You can ask your health care provider for details.

Select Trial Requirements

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 eligible. If you meet all of these, 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
- 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

Trial Duration

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

Schedule of Visits

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, you 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