



Patient's Guide to **Arthrex ACP[®]**
Autologous Conditioned Plasma
and Knee Osteoarthritis
Clinical Study



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I. What is Knee Osteoarthritis (OA)?

Knee OA is a condition in which the natural cushioning between joints (cartilage) wears away. As this happens, bones of the joints rub against one another without the shock-absorbing benefits of cartilage. The rubbing results in pain, swelling, and stiffness. This pain can lead to decreased mobility and inability to function.

II. What causes Knee Osteoarthritis?

The most common cause of knee OA is age, though several other factors increase the risk of developing arthritis at an earlier age. Weight plays a role as it increases pressure on all the joints, especially the knees. Other factors include heredity, repetitive stress injuries, athletics and other illnesses.

III. What are common treatments?

One of the most effective ways to treat this wear and tear arthritis is weight management. Your weight could have a large impact on how you and your joints feel. Managing a healthy diet and getting regular exercise could benefit your knee OA as well. Additional treatment options include, but are not limited to the following:

- Non-drug pain relief techniques
- Medications
- Alternative therapies
- Surgery

IV. Treatment groups

An automated Internet-based randomization system will ensure concealed randomization of eligible consenting subjects. Subjects will be randomized to one of two treatment groups.

Investigational Treatment (Autologous Conditioned Plasma - ACP)

Autologous Conditioned Plasma is a concentration of platelets and growth factors created from a small amount of your own blood. Increased levels of growth factors improve signaling and recruitment of cells to an injury site and optimize the environment for healing. Often referred to as platelet rich plasma (PRP), this treatment has been used to assist in the treatment and recovery of injuries.

Your health care provider will draw a small amount of blood from your arm using a needle and a specially designed syringe. The blood then goes through a rapid spinning process that separates and concentrates the platelets and other beneficial growth factors from the blood. The plasma containing these platelets and growth factors is injected into the joint and applied to the treatment area. The entire ACP process is usually done in less than 30 minutes.

Placebo Treatment (Normal Saline)

The placebo is a sterile solution of sodium chloride (table salt) and water.

V. Visits and follow-ups

As a participant in this research trial, all subjects will have a screening visit and three treatment visits to receive a series of intra-articular injections one week apart. Participants must then return to the clinic for follow-up visits. These visits will take place at two months, three months, six months and 12 months from the first treatment.

Screening visit:

The research team will have the following data collected and procedures conducted:

- The signed informed consent
- Your health history information and perform a physical exam
- A urine pregnancy test (females with childbearing potential)
- List of current medication and treatments
- The WOMAC survey regarding (pain, stiffness, function)
- X-rays if not already part of medical record

The research team will have the following data collected and procedures conducted at each follow-up visit:

- The WOMAC survey regarding (pain, stiffness, function)
- Medication and treatments
- Information regarding any adverse events or complications

Treatment visits:

Visit 2: The treatment you receive will be determined by random selection, like drawing straws. In this study you will have a 2 to 1 chance of receiving the ACP treatment or the placebo treatment at one week intervals for three weeks. Both treatments will require your own blood and no matter which treatment you receive, the follow-up visits will be the same. You, the physician, and the coordinator will not know which treatment you receive until 12 months after the initial treatment after the initial treatment.

Visit 3: One week from Visit 2

Visit 4: Two weeks from Visit 2

Follow up visits:

Visit 5: Two months from Visit 2

Visit 6: Three months from Visit 2

Visit 7: Six months from Visit 2

Visit 8: Twelve months from Visit 2





VI. Risks, side effects and discomforts

There are risks associated with this procedure are similar to any joint injection which your study doctor will explain to you. The risks associated with the procedure include but are not limited to difficulty drawing blood through the syringe during the blood draw, and difficulty depressing the plunger of the syringe during the injection procedure. The result of either of these two events occurring would be an additional needle stick.

There are other risks associated with the ACP which are listed below:

- Infections, both deep and superficial
- Allergies and other reactions to device materials
- Bruising
- Joint pain
- Joint stiffness
- Increased fluid around or within the knee (joint effusion)
- Joint swelling
- Joint warmth
- Injection site pain
- Blood vessel damage
- Nerve damage
- Arthritis
- Joint disease
- Change in normal walking

Because the ACP is an experimental treatment, there may be other risks that are unknown at this time. You should always talk to your study doctor about any risks or concerns that you may have.

The ACP Double Syringe System was cleared by FDA (REF. No BK070069) in 2008 for the preparation of PRP to be mixed with bone graft material. The device has not been cleared for the indication, "Pain relief from osteoarthritis of the knee", as proposed in this study.

VII. Common questions about research studies

Q. What is a research study?

A. A research study is an organized activity to learn more about a problem or answer questions. A research study may be done to find out what health care practices work best. It may also be done to determine the best way to prevent illness. A clinical trial is a research study that will try to decide whether new treatments are safe and effective. In clinical trials, treatments are often compared with placebos to check the effectiveness of that treatment.

Q. Should I take part in a research study?

A. Thousands of research studies are conducted each year. These studies have contributed to health improvements for many people. In addition, your participation could further knowledge of scientific research and medical care.

Q. Why should I volunteer for a research study?

A. There are many reasons to participate in a research study. You may want to: help find a cure for an illness, help other people who are sick, help find ways to provide better care and treatment options.

Q. What is informed consent?

A. Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your participation is completely voluntary and confidential.

Q. Are there benefits to being in a research study?

A. There may or may not be a direct benefit if you take part in this research study. No one can predict what will happen or how it might affect you. The research study may result in information that will help others in the future.



VIII. Questions for your doctor

Doctor's Name _____

Doctor's Telephone Number/Address _____

Research Coordinator's Name _____

Research Coordinator's Telephone Number/Address _____

Questions/Comments



For more information on the trial please visit:
www.ACPClinicalTrial.com