

Do you have chronic pain in your hip?

Ask the Research Staff about the

MONOVISC®

Hip Osteoarthritis Study

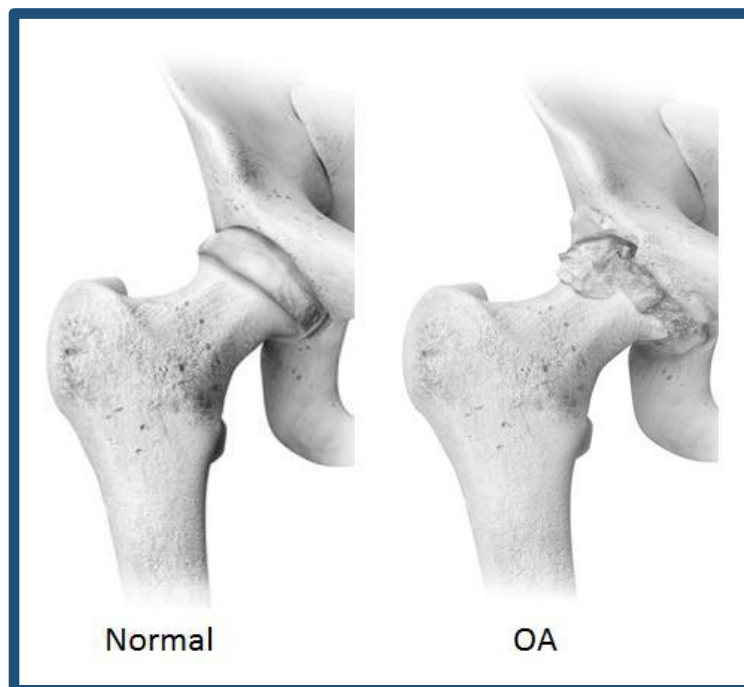
for people with osteoarthritis (OA) of the hip.

You may qualify for the MONOVISC Hip OA study if you:

- are at least 30 years old
- have hip osteoarthritis that causes significant walking pain
- are willing to discontinue all pain medications for the duration of the study except for acetaminophen (e.g. Tylenol)
- have not had recent injections into your hip joint

Other study restrictions apply.

Investigational MONOVISC will be provided at no cost.



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MONOVISC[®] **Hip Osteoarthritis Study**

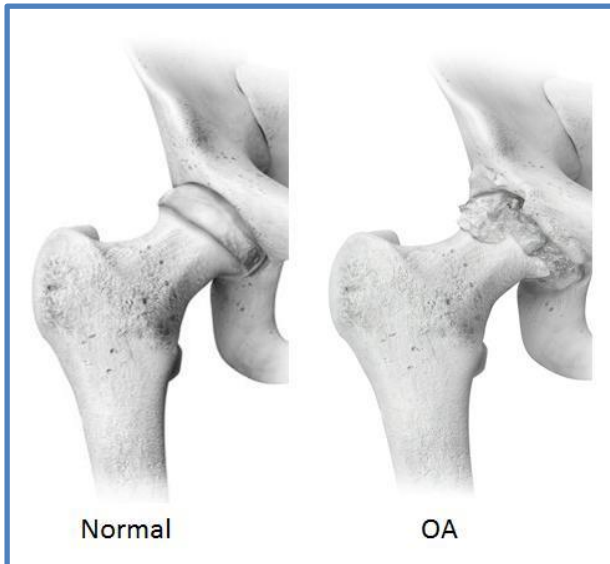
for people with osteoarthritis (OA) of the hip.

What is hip osteoarthritis?

Osteoarthritis (OA) is a painful degenerative condition of the joints. It can affect any joint in the body, but it is most common in the knees, hips and hands.

When osteoarthritis occurs in the hip, the structures of the ball-and-socket joint begin to deteriorate, leading to inflammation and breakdown of the tissues that enable the hip joint to move freely. The result can be significant hip pain, which can decrease your ability to walk, run, sleep or to perform normal daily functions.

Treatments for hip pain include physical therapy, exercise and weight loss, anti-inflammatory medications, or simple analgesics (pain medication). For some hip OA patients, medications injected directly into the joint can provide significant relief from OA pain and symptoms. For other patients, the only alternative is surgical replacement of the hip joint with an artificial joint.



What is the MONOVISC Hip OA Study?

The MONOVISC Hip OA study is being conducted to determine the effectiveness of **investigational MONOVISC®** High Molecular Weight Hyaluronan for the relief of pain and symptoms of osteoarthritis of the hip. Specifically, the study will determine if MONOVISC is more effective than a control treatment when delivered as intra-articular injections (injected directly into the hip joint). In this case, the control treatment will be a dilute solution of salt water (saline).

Patients in the study will be required to participate in follow up visits every few weeks for six months following their injections, so that they can report to their study doctor on their hip OA symptoms.

Only patients with mild-to-moderate hip OA, as determined by a hip X-ray, will be eligible to participate. If your hip joint is only in its initial stages of osteoarthritis, or if it is extremely deteriorated, you may not be eligible.

Can I participate in the MONOVISC Hip OA Study?

Only a study doctor will be able to determine for sure whether or not you will qualify to participate in the study. Some of the basic

requirements for participation include:

- You must be diagnosed with osteoarthritis in your hip that results in significant pain when you walk
- You must be willing to take only acetaminophen (Tylenol) for hip OA pain while you are in the trial
- You must be willing to stop taking pain medications for 2 days prior to each follow up visit
- You must not have had recent injections into your hip

How will the MONOVISC Hip OA Study work?

After your study doctor has determined that you are eligible for the study, you will be placed into one of two groups. This study is randomized, meaning that there is a chance that you will get MONOVISC injections and a chance that you will get saline injections. Specifically, you will have a 67% chance of getting MONOVISC injections, and a 33% chance of getting saline injections.

Patients who participate in the MONOVISC study will receive two injections directly into their painful hip. The injections will be separated by one month. Over the course of the six month study, patients will be required to visit

their study doctor six times. This includes the two injection visits. At each of these visits, you will be asked to fill out questionnaires about your recent hip OA symptoms. You will also be asked to report any side effects that you may have experienced from your injections.

During this study, you will only be allowed to take acetaminophen (e.g. Tylenol) to control your hip pain. You will be asked to keep a diary of the amount of acetaminophen you take, and how often you take it, to control your hip pain.

Why is MONOVISC being studied as a therapy for hip OA?



The main ingredient of MONOVISC is hyaluronic acid (HA), also known as hyaluronan. Hyaluronic acid is a naturally occurring substance that is an important component of synovial fluid. Synovial fluid is a liquid that bathes the tissues inside the hip joint, helping to lubricate the cartilage in the joint and enabling the joint to easily flex. In patients with osteoarthritis, the amount of HA in the synovial fluid is often reduced, which can contribute to pain, stiffness, and loss of function in the osteoarthritic joint.

Intra-articular injections of HA (injected directly into the joint) can help replenish synovial fluid HA, and have been shown in many clinical studies to help reduce pain and restore mobility to patients with osteoarthritis of the knee. We hypothesize that HA injections into the hip could have similar positive effects for hip OA patients.

Why should I participate in the MONOVISC Hip OA study?

The possible benefits of participating in the MONOVISC Hip OA study include:

- This study will help us learn if MONOVISC is an effective therapy for people suffering from hip OA
- You may experience significant relief from your hip OA symptoms.
- You will be helping others by contributing to important medical research

What are the risks of participating in the MONOVISC Hip OA Study?

Before you agree to participate, your doctor will provide you with a complete list of all possible side effects. Most of these risks are anticipated to be minor and

temporary. Some of those possible side effects include:

- Pain, stiffness or swelling at the injection site
- Injection site infection
- Nerve or tissue damage resulting from the injection procedure

Before you agree to participate in the study, your study doctor will review all of the possible risks and benefits.

What else should I know about the MONOVISC Hip OA study?

While your hip OA symptoms may improve as a result of your participation in the study, there is no guarantee. Your symptoms may not change at all, or they may become worse.

If you do not have health insurance, you may not be eligible to participate. The study sponsor will provide the MONOVISC or saline that is injected into your hip at no cost to you. You will also be compensated for transportation and other costs associated with your visit. However, routine procedures associated with the injections must be paid for by you or your insurance. Your study

doctor will discuss the details of study costs with you before you agree to participate.

Will my privacy be protected?

Study doctors and their staff will respect your privacy. Details about your condition will only be shared with people who are directly associated with the MONOVISC Hip OA Study. Your study doctor will provide more specific information about how your personal health information will be protected. Your study visits will be conducted in medical offices under the supervision of a doctor and in compliance with all regulatory requirements.

If you are interested in learning more, ask your doctor about the

MONOVISC[®] Hip Osteoarthritis Study



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