

Clinical Trial Study



A Guide to the Informed Consent Process



What is Gene Therapy?

There are different types of gene therapy being used in medicine and research today. For this study:

- It is based upon a small virus called adeno-associated virus, or AAV (also called a 'vector').
- AAV is not known to cause disease.
- This virus has been changed in the laboratory so that it is not likely to reproduce.

The virus acts as a delivery driver (like a taxi, Uber, UPS, or FedEx) to deliver genetic material (a package) to your cells.





Clinical Research

- This is done to see if it is safe and how it interacts with your body.
- This clinical research study is supervised by certain regulatory bodies such as the US Food and Drug Administration and other committees who are responsible for the safety and welfare of study participants.
- The study staff has a duty to protect your rights as a participant should you choose to participate:
 - ◇ You may choose to leave the study at any time without any penalty or loss of benefits to which you might have been otherwise entitled.
 - ◇ All known potential risk and benefits are closed to you in the ICF.
 - ◇ Your identity and personal information will be protected and kept confidential.
 - ◇ The study treatment will be provided at no charge.

Clinical Trial

This study is testing a new possible treatment for osteoarthritis (OA).



1. The package of genetic material is a code (like a set of instructions) for your cells to build more of a naturally occurring molecule (something that your body makes already) called interleukin-1 receptor antagonist (IL-1Ra)



2. IL-1Ra competes (like a race) with another molecule in your body called interleukin-1, which is a molecule that is thought to make OA get worse. There is an increased amount of IL-1 in patients with knee OA.

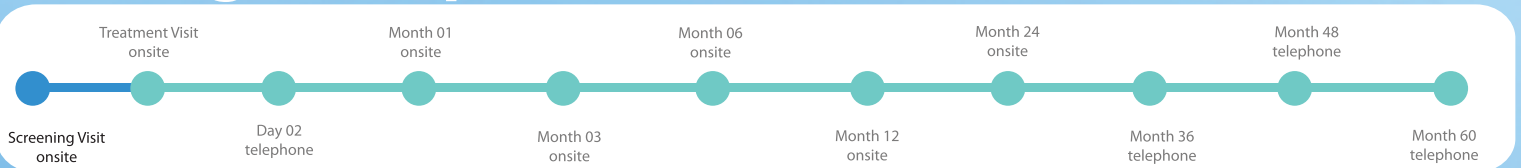


3. When IL-1Ra wins the race it blocks interleukin-1 from working. If IL-1Ra wins more than interleukin-1 then your OA should get better.





What will happen in this study during each period?



During this visit, we will do some tests and procedures to see if you can take part in this clinical research study. The study doctor will review the results of these tests and procedures. If you do not qualify, you will be told why.

Screening Visit (After Study Consent):



Medical History



Physical Exam
+ Vital Signs



Questionnaires



Bloodwork/
Urine Sample



Knee Ultrasound



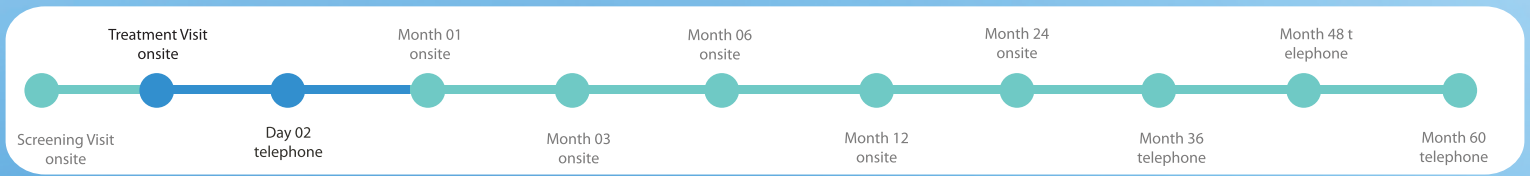
Knee X-Ray



Knee Examination

Please note that it is possible that more than one visit to the research site may be needed in order to complete all planned tests and procedures.

What will happen in this study during each period?



Treatment Visit (Day 1-After Confirmed Eligibility)



Physical Exam
+ Vital Signs



Knee Examination



Questionnaires



Bloodwork/
Urine Sample



Synovial Fluid
Collection



Study Injection



Knee Ultrasound

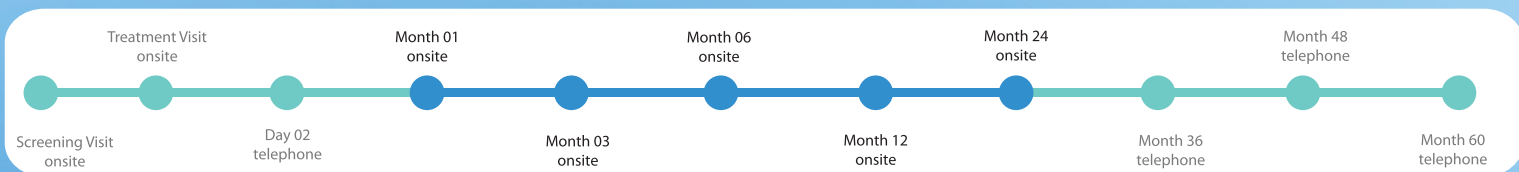


Day 02 Telephone:

- Study staff will check in to see how you are doing.
- They may ask questions about any changes in your health or drugs you have taken since your last visit and other serious medical conditions.



What will happen in this study during each period?



Onsite Post-Treatment Follow Up Visits (Through Month 24):



Physical Exam
+ Vital Signs



Knee Examination



Questionnaires



Bloodwork/
Urine Sample



Synovial Fluid
Collection



Knee Ultrasound



What are my next steps?

Read the informed consent form (ICF) and make sure all of your questions are answered by the study staff.

If you choose to participate:

- Sign the ICF, you will receive a copy.
- Complete or schedule the screening visit.

Thank You!

Thank you for considering participating in this study.
The study staff will now take you through the rest of the ICF process.