What is Limited JIA?

The word "arthritis" means **inflammation (swelling) and stiffness of the joints**. Arthritis that affects children under the age of 16 is known as juvenile idiopathic arthritis, or JIA.

Oligoarticular JIA (also known as limited JIA) is the most common type of JIA. It affects **four or fewer joints during the first six months**. After the first six months, some patients may have more than four joints affected; this is called extended oligoarticular JIA.

JIA can be very **difficult to diagnose**. No one test can confirm the diagnosis, so doctors need to use a few tests and a physical exam to rule out any other reasons for a child's joint pain.

So, what does having JIA look like? Over time, patients with limited JIA notice that **their joints are more affected by arthritis**. Patients will experience pain, swelling, stiffness, and possibly even damage to the joint bones and cartilage. Over time, certain joints may need to be replaced.

JIA can also affect a patient's eyes, so children need to visit an eye doctor right after they are diagnosed and often after that to make sure they do not have eye disease connected to their arthritis.

Thankfully, after the long process of getting a diagnosis, **you can begin treating JIA right away** to slow or pause its progression (spreading).

There are **many effective treatments** that can allow your child to live a happy and healthy life, and in his or her lifetime, **your child will try many of them**. Medication for arthritis in children has improved a lot in recent years, and **research is helping us learn more** about the condition all the time.

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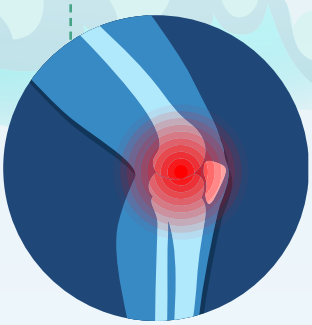
Treatment Options


JIA affects the joints, such as the knee.

The JIA Usual Care

Because limited JIA affects only a few joints, doctors often start treatment with injections of medicine into the swollen joints, sometimes along with a drug to reduce swelling such as ibuprofen (Advil, Motrin) or naproxen (Aleve, Anaprox, Naprosyn) which are called nonsteroidal anti-inflammatory drugs.

Some medications for oligoarticular JIA are:

Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, to ease pain and lower inflammation. These are taken in tablet or liquid form.

Corticosteroids, such as prednisone, to lower swelling. These can be given as tablets, liquid, injection into the joint, or drops into the eye.

Disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate, to stop arthritis from spreading can be taken in tablet or liquid form or by injection.

These are some of the most common treatments for oligoarticular JIA, meaning they are the usual care. Even with usual care, **JIA can still spread** and get worse. About half of all oligoarticular JIA patients will experience disease spreading to more joints, uveitis (inflammation of the eyes), or both.

Researchers working with parents are **exploring options** which may prevent the disease from spreading better than the usual care.

The Limit-JIA Clinical Trial

Abatacept (Orencia) is a biologic disease-modifying anti-rheumatic drug (DMARD) used to treat JIA when it starts affecting more joints. In this case, **we believe using abatacept earlier will help prevent JIA from spreading**.

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About the Study

What Will the Study Involve?

The Limit-JIA clinical trial takes **a total of 12 months**. During that time, your child will be given 6 months of weekly abatacept injections followed by 6 months of the usual care.

The study also involves **a few scheduled visits.** There will be 1 *screening visit* to see if your child is a good fit for the clinical trial, 1 *check-up visit*, 4 *scheduled appointments* 3 months apart, and 2 to 4 *ophthalmology (eye doctor) visits* (depending on the participant). There may also be additional doctor's visits as needed. Finally, parents will be asked to complete surveys related to their child and keep records of all medications their child takes for their JIA.

Benefits vs. Disadvantages

If you choose to join the study, there are pros and cons related with participation. Let's weigh the choices.

Benefits include:

- Education, support, and feeling good about helping researchers
- Close follow-ups from the care staff
- Access to treatment not available to others
- Treatment provided at zero cost
- A chance to help other patients with JIA

Disadvantages include:

- Chance of having a side effect(s) from taking the study drug abatacept.
- Chance the drug will not work
- Taking additional time for activities like surveys, etc.

Discussion Guide

To learn more about the study, you can **talk to study coordinators (people who help patients before and during a clinical trial)**. Here are some questions you may want to ask the coordinator. More questions—and answers!—can be found in this packet.

1. How long is the trial? How often do I have to visit the study site and how long will each visit take compared to what I would do usually?
2. What else do I have to do while in the study?
3. What is known about the short-term and long-term side effects of this drug?
4. Are there other treatments for my child's condition?
5. Will the lab tests cost me anything? Will I get the results of these tests?
6. Will I get any money for joining the clinical trial?
7. Will I get the study drug once the trial is over?
8. Who do I call if I have a problem with how I am treated while in the clinical trial?

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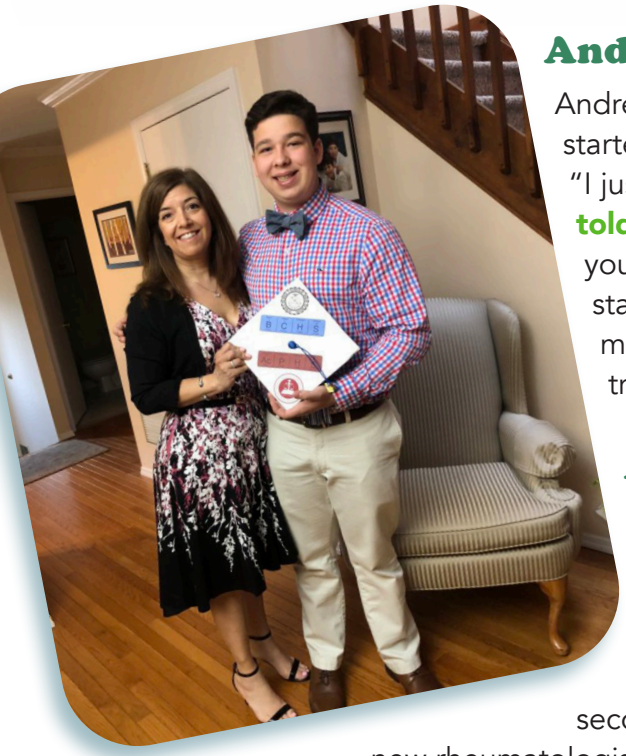
Parent Testimonial

When Laura's son, Andrew, was two years old, she took him to the pediatrician with what she thought was a minor injury to his ankle. When it never healed, she decided to take him back in. She says, "The pediatrician *really* looked at him this time. He said, 'I'm going to send him in for blood work, and I'm going to test him for everything possible, but **my gut is that he has arthritis**.' When we first got the diagnosis, I was pretty much in shock. People didn't know that little kids can get arthritis."



Andrew's First Treatments

Andrew began seeing a rheumatologist who started him on a standard treatment plan. "I just kept putting him on **whatever they told me to do...** Because, at the end of the day, you just want your child to have a good quality of life. Then we just started going through every NSAID imaginable. And then disease modifiers. Between the ages of 2.5 and like 8 years old, he probably tried every single NSAID And DMARD that you can think of."

A Commitment to Research

"I was **getting concerned** because we couldn't get Andrew's ankle under control no matter what we tried, and he was in first grade at this point." Finally, she decided to get a second opinion. At the new rheumatologist, Laura and Andrew were **involved in research from day one**. "Any study that was happening, we signed up, because we really do believe in sharing the information," Laura recalls. "It's not going to change what he went through in the past, but if another little 2-year-old doesn't have to go through some of the things that he went through, then… **I'm all for sharing and letting others know** what our outcomes have been."

Questions & Answers

Why are we doing Limit-JIA?
Treatment for JIA has come a long way in the last 20 years, with many medications available now to slow or stop the disease. But, usual care of oligoarticular JIA still results in JIA getting worse for about half the children. After JIA gets worse by spreading to more joints or the eyes, children are given a medication like abatacept (Orencia). We want to learn if we can prevent JIA from getting worse by using abatacept (Orencia) as soon as they are diagnosed with oligoarticular JIA.

What is a clinical trial?
A clinical trial is designed to answer specific questions about possible new treatments or new ways of using existing (known) treatments. In Limit-JIA our question is "Can we prevent oligoarticular JIA from getting worse by using abatacept (Orencia) in the beginning?"

What kind of drug are we testing?
Abatacept (Orencia) is approved by the Food and Drug Administration (FDA) to treat moderate to severe JIA. We are testing to see if using it earlier can help prevent JIA from getting worse which happens to about half the children getting usual care.

Are there any costs or payments if my child participates in the study?
Any usual care costs will be covered by you or your insurance company, as normal. Costs associated with the trial will be paid for by the study. This includes abatacept (Orencia), study visits, and study lab tests.

What are the risks?
Because abatacept (Orencia) is approved by the FDA and has been used to treat JIA since 2008, the risks are well understood. Infection (primarily upper respiratory tract) and reactions at the injection site are the most common side effects.

What happens if I decide to withdraw after the trial begins?
You will stop getting the abatacept (Orencia) but will continue to receive usual care.

What happens if my child needs to stop taking the abatacept (Orencia)?
There may be a reason for your child to stop taking the drug. If this happens, we will make sure your child continues to receive time and attention associated with the trial. During this time, we will still collect important safety and clinical data.

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Abatacept Log

If you have any problems with or questions about your injections, please refer to your injection guide for contact information for your local site.

Date and Time of Study Injection

Injection Administration

Date	Dose (color of plunger)	Injection sites (arm, thigh, or tummy—indicate left or right side)	Was full amount injected? (Yes or No)
4/23/19	*blue*	*left arm*	*yes*

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About Uveitis

Uveitis

In addition to joint inflammation (called arthritis), **eye inflammation** (called uveitis) can develop in children with juvenile idiopathic arthritis (JIA). If not treated, uveitis can cause vision loss or blindness. Children with uveitis often do not have symptoms, such as pain, redness, or trouble seeing, so **regular eye exams** by a pediatric eye doctor (ophthalmologist) are necessary.

Eye Exams

The eye doctor will use special equipment to magnify the structures in the eye to see if there is inflammation or damage. The eye doctor will perform a **"slit-lamp" exam**—a painless test where a green light is shined through a microscope to examine the inside of the eye. If there is inflammation, the doctor will report the number of cells that they see. The number of cells indicates the amount of eye inflammation present. Sometimes eye drops are used to enlarge the eye to make it easier to see inside.

How Often

Children with oligoarticular JIA have the highest chance of developing uveitis and need to be checked by the eye doctor most often, however **uveitis happens in all forms of JIA**. Depending on your child's JIA type, age, and antinuclear antibody (ANA) status, they may need to be checked **every 3 months**. Eye exams can detect inflammation early, so that treatment can start before permanent damage and loss of vision.

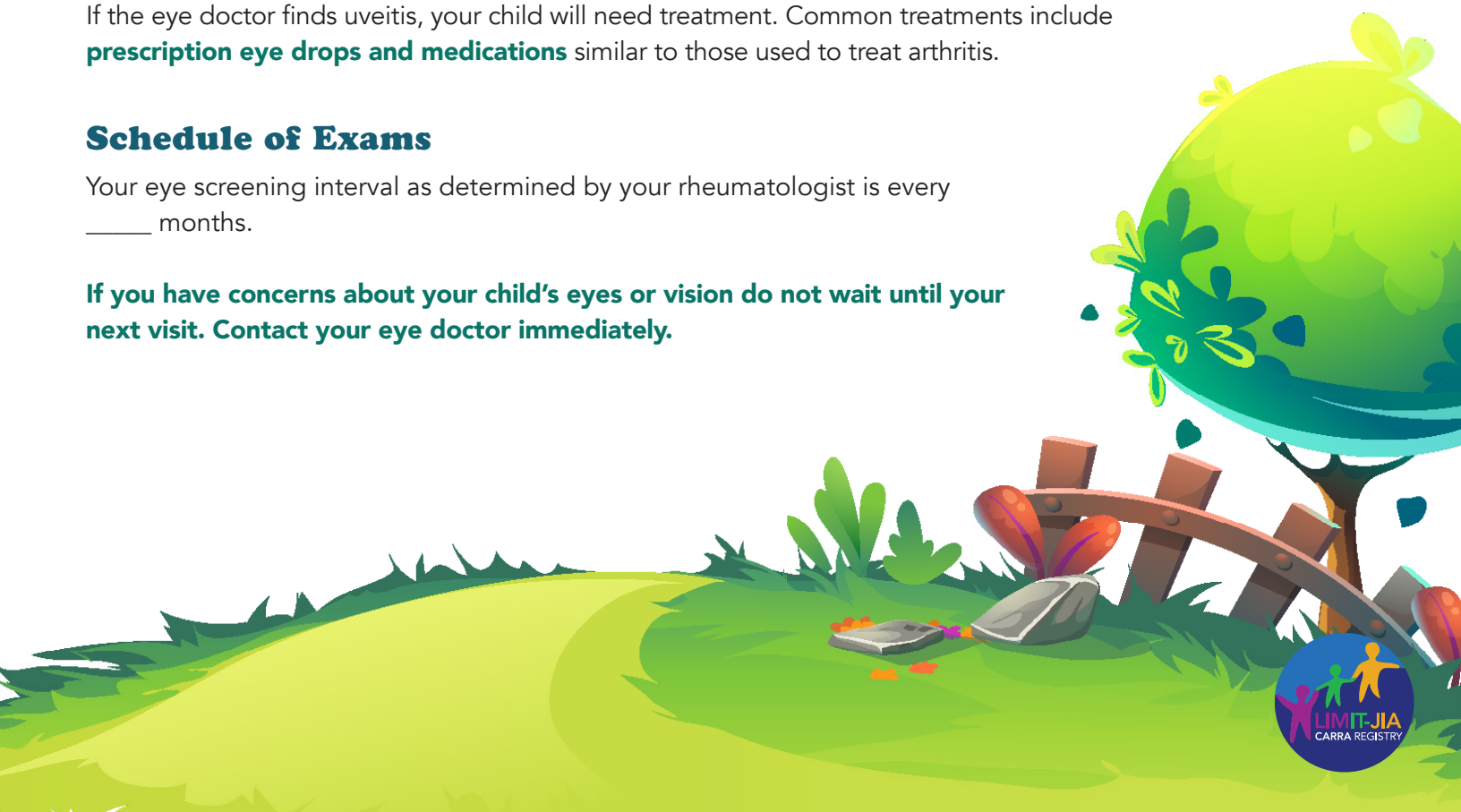
Treatment

If the eye doctor finds uveitis, your child will need treatment. Common treatments include **prescription eye drops and medications** similar to those used to treat arthritis.

Schedule of Exams

Your eye screening interval as determined by your rheumatologist is every _____ months.

If you have concerns about your child's eyes or vision do not wait until your next visit. Contact your eye doctor immediately.



Uveitis Survey

Date _____

At your eye doctor visit today, did your doctor tell you that you have active inflammation (called uveitis or iritis) in your eyes?

☐ Yes ☐ No **If YES, fill out the survey below. If NO, stop here. Thank you for your participation!**

In which eye(s) did your doctor say you have active inflammation?

☐ Left Eye	☐ Right Eye
What is the cell count for your left eye? ☐ 1–5 ☐ 6–15 (1+) ☐ 16–25 (2+) ☐ 26–50 (3+) ☐ > 50 (4+)	What is the cell count for your right eye? ☐ 1–5 ☐ 6–15 (1+) ☐ 16–25 (2+) ☐ 26–50 (3+) ☐ > 50 (4+)

Does your eye doctor recommend adding a medication because of the inflammation in the eyes?

☐ Yes ☐ No

Is your vision affected by the inflammation?

☐ Yes ☐ No

Did your doctor say that you had eye scarring or signs of inflammation in the past?

☐ Yes ☐ No

End of Survey. Thank you for your participation!

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