

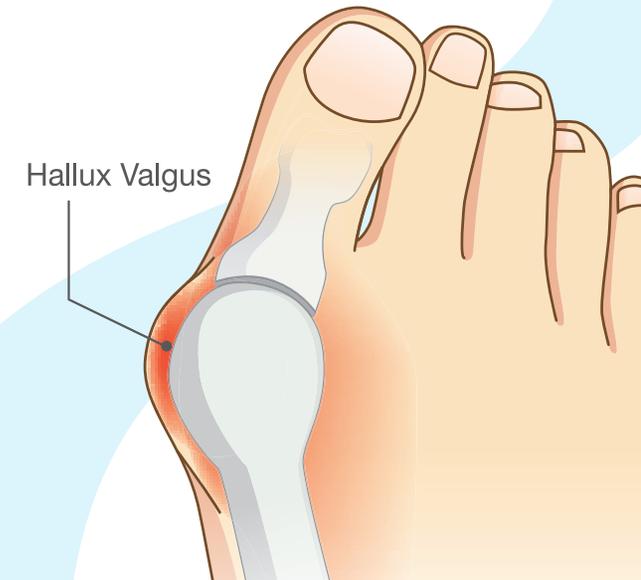
 **Dystance**



## What is a bunion?

- A bunion is a bony bump that forms on the muscle joint of the big toe.
- **Common causes:** tight shoes, foot stress, arthritis, age, or genetics.
- **Symptoms:** bone deformity, pain, and stiffness.
- **Current treatment options:** changing shoes, using orthotic devices or splints, taking over-the-counter inflammatory medication, or having surgery.
- The Dystance study will evaluate whether the study medication can provide an effective treatment alternative for subjects with bunions.

 **Dystance**



Learn more about a research study named  
**Dystance**  
for enrolling  
patients  
with bunions

For more information about the Dystance study, visit [footbunionstudy.com](http://footbunionstudy.com) or contact:



## What is the Dystance study?

The Dystance study will investigate the effectiveness of an investigational drug compared with placebo (without any active ingredient) in adults with hallux valgus (HV), more commonly known as a bunion.

## What is the study medication?

The study medication is considered investigational in the Dystance study because it has not yet been shown to be effective and has not been approved by the FDA to treat bunions.

## Who can participate in the study?

You may be eligible to participate in the Dystance study if you meet these criteria\*:

- 18 years of age or older
- Have been diagnosed with bunion(s)
- Have been treated for bunion(s), but have NOT had foot surgery
- No medical history of diabetes
- No allergies to cow's milk protein

\* Other criteria will apply.

## What will happen if you join the study?

If you are eligible and decide to participate in this study, you will first be randomly assigned (like the flip of a coin) to receive either one of 2 doses of the study medication containing the active ingredient or the placebo (which has no active ingredients). Neither you nor the study staff will know to which treatment group you have been assigned (Double-Blind). After the treatment day, you will have a follow-up visit one week later.

- The Double-Blind Period will last for 12 weeks.
- The study medication is administered by injection into the muscles of your foot with the bunion. If both feet have a bunion, you will receive study treatment in the foot that is deemed to have a more severe bunion. Your other foot will not be treated in this study.
- You may receive up to 2 subsequent injections of the study medication containing the active ingredient (with 12 weeks between each injection), if you are eligible for retreatment (for up to a maximum of approximately 9 months).

During the study, you will be asked to report your symptoms from home and will be expected to attend study visits at the study site where the study staff will monitor your health, take blood and urine samples, and measure bone angles of your foot by x-ray.

To find a description of this study, visit: [clinicaltrials.gov](https://clinicaltrials.gov), study ID: NCT03569098.

## A note on clinical research

- Clinical research studies help scientists and doctors evaluate the safety and effectiveness of a study medication for certain conditions.
- These studies rely on clinical study volunteers like you.
- Your participation in this study is voluntary, and you can decline participation without penalty or loss of any benefits for which you are entitled. You may stop participation at any time.
- You should only enroll in the Dystance study after careful discussion with a study doctor and after all your questions have been answered satisfactorily.

The logo for Dystance, featuring a stylized blue wave icon to the left of the word "Dystance" in a bold, dark blue sans-serif font.