A Study to Investigate the Safety, Tolerability and Preliminary Efficacy of NGI226 Microparticles in Patients With Achilles Tendinopathy

Last Update: Jul 11, 2025
A Two Part, Randomized, Participant and Investigator-blinded, 2-arm, Parallel-design, Placebo-controlled Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of NGI226 Microparticles on Tendon Regeneration in Patients With Achilles Tendinopathy
ClinicalTrials.gov Identifier:
NCT05592990
Novartis Reference Number:CNGI226A12201
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to measure local and systemic safety and tolerability as well as improvement of Achilles tendon mechanical properties after a single peritendon injection of NGI226 MP in comparison to placebo MP in patients with mid-portion Achilles tendinopathy.

Condition
Achilles Tendinopathy
Phase
Phase2
Overall Status
Recruiting
Number of Participants
46
Start Date
Jun 14, 2023
Completion Date
Feb 10, 2026
Gender
All
Age(s)
30 Years - 70 Years (Adult, Older Adult)

Interventions

Drug

NGI226

NGI226 MP
Drug

Placebo

Placebo MP

Eligibility Criteria

Inclusion Criteria:

* Written informed consent must be obtained prior to all study specific screening procedures, as close to the start of the screening period as possible.
* Presence of clinically (local Achilles tendon pain on tendon-loading activities, pain on palpation at the level 2-6 cm proximal to the calcaneal insertion) and ultrasound (local tendon thickening with hypoechogenicities and irregular fibre orientation) or MRI diagnosed mid-portion Achilles tendinopathy with symptoms present ≥8 weeks but \<12 months at screening.
* The Achilles tendinopathy must have been refractory to at least 6 weeks of conservative treatment (physiotherapy, NSAIDS, RICE), but participants do not need to be in physiotherapy at the time of study entry.

Exclusion Criteria:

* Medical condition that would affect safety of peritendon injection (e.g., peripheral vascular disease, use of anticoagulant medication)
* History of recurrent, acute, symptomatic infections, including outbreaks of oral or genital herpes (\> 2 symptomatic infections or \>2 courses of anti-infective treatments required in the last 6 months; active systemic infection during last 2 weeks; known active infections (e.g. chronic or active Hepatis B or C, HIV) - simple cold excluded
* History or evidence of clinically significant cardiac or cardiovascular disease
* History of deep vein thrombosis, pulmonary embolism or evidence of primary or secondary hypercoagulable states
* History of surgical intervention for the treatment of tendinopathy, history of ankle surgery, ankle arthritis, traumatic, inflammation or deformity of ankle
* History of full-thickness tear or complete rupture of the Achilles tendon

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05592990*

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