NOVARTIS

Study of Safety, Tolerability and Clinical Outcomes of Egaten in Fascioliasis Patients (6 Years of Age or Older).

Last Update: May 21, 2025

A Phase IV, Multi-center, Open-label Study to Determine the Safety, Tolerability and Clinical Outcomes Following Oral Administration of EGATEN™ (Triclabendazole) in Patients (6 Years of Age or Older) With Fascioliasis.

ClinicalTrials.gov Identifier:
NCT04230148

Novartis Reference Number:CEGA230B2404

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

This is a multicenter, open label, non-comparative, single arm multi-country study in approximately 300 adult and pediatric subjects (≥ 6 years of age) with fascioliasis. The study population consists of male and female adult and pediatric patients (≥ 6 years of age). The study will enroll approximately 300 subjects with acute (minimum 15% of overall study population) or chronic fascioliasis. Enrolled subjects will receive two doses of 10 mg/kg of Egaten given approximately 12 hours apart. Subjects will be treated and followed up on an outpatient basis. After screening and post treatment, at Day 3 and Day 6 the subjects will be followed for safety and tolerability. These visits are primarily for safety follow up and may be telephonic or home visit by qualified personnel or onsite visits based on the investigator's discretion. During visits Day 10, Day 30, Day 60 and Day 90 post-treatment, the subjects will be followed for safety, tolerability and efficacy. On Day 15, Day 45 and Day 75, telephonic follow-up (primarily for safety) will be conducted.

Condition
Fascioliasis
Phase
Phase4
Overall Status
Recruiting
Number of Participants
300
Start Date
Feb 11, 2022
Completion Date
Dec 09, 2026
Gender
All

Age(s)
6 Years - 99 Years (Child, Adult, Older Adult)

Interventions

Drug

Egaten (Triclabendazole) 250 mg tablets

Egaten 250 mg scored tablets for oral use.

Eligibility Criteria

Inclusion Criteria:

1. Written informed consent must be obtained before any study protocol specific assessment is performed.

1. Parental/legal guardian informed consent must be obtained and signed for pediatric subjects (formally documented and witnessed, via an independent trusted witness) prior to any study related procedure.
2. Subjects \< 18 years old, who are capable of providing assent, must provide assent with parental/legal guardian consent or as per local ethical guidelines.
3. If the subject is unable to read and write or otherwise incapable of signing an informed consent, then a witnessed consent according to local ethical standards is permitted.
2. Subjects (Adult and pediatric subjects ≥ 6 years of age and above 12.5 kg of weight) at time of consenting must have been diagnosed with fascioliasis based on clinical signs, symptoms and laboratory evaluations as per local clinical practice.

Exclusion Criteria:

1. Subjects diagnosed with ectopic fascioliasis, extrahepatic involvement (e.g., lungs, spleen, pancreas, subcutaneous tissue, gastrointestinal organs, etc.).
2. Subjects with known hypersensitivity to triclabendazole /other benzimidazole derivatives and/or any of the excipients in Egaten.
3. Subjects taking any anthelmintic medications within two weeks or 5 half-lives, whichever is longer prior to enrolling into study.
4. Inability or unwillingness to undergo study related procedures.
5. Subjects who in the judgment of the Clinical Investigator are unsuitable for the trial or who have to be excluded in order to be compliant with local fascioliasis management guidelines that may differ from the FDA approved label, including but not limited to :

1. Subjects who are machine operators or drivers.
2. Medical history of liver (other than fascioliasis), kidney or cardiac disease.
6. Females (including under the age of 18) known to be pregnant or testing positive for pregnancy at screening.
7. Lactating women unwilling to discontinue lactation up to 72 hours after the second dose administration or as per local guidelines.
8. Subjects requiring therapeutic drug monitoring of CYP2C19 substrate(s) (e.g. S-mephenytoin).
9. Subjects with medical history of QT prolongation or a history of symptoms compatible with a long QT interval or on medication which prolong the QT interval.

Colombia

Novartis Investigative Site

Recruiting

Medellin,Antioquia,050010,Colombia

Egypt

Novartis Investigative Site

Recruiting

Alexandria,21131,Egypt

Peru

Novartis Investigative Site

Recruiting

Cusco,84,Peru

Vietnam

Novartis Investigative Site

Recruiting

Quy Nhon,Binh Dinh,590000,Vietnam

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct04230148*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT04230148
2. #trial-eligibility
3. tel:+41613241111
4. mailto:novartis.email@novartis.com