Specified Drug-use Surveillance of Fabhalta Capsules

Last Update: Jan 14, 2025
Specified Drug-use Surveillance of Fabhalta Capsules (Paroxysmal Nocturnal Hemoglobinuria, CLNP023C11401)
ClinicalTrials.gov Identifier:
NCT06606314
Novartis Reference Number:CLNP023C11401
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, single-arm, non-interventional study (NIS) with a central registration system and an all-case surveillance system. The observation period is 48 weeks after the start of treatment with Fabhalta. The observation period will be 48 weeks after the start of treatment with Fabhalta.

For patients in whom treatment with Fabhalta is discontinued within 48 weeks after the start of the treatment, adverse events occurring by the last day of the treatment + 30 days and concomitant drugs will be monitored and recorded in CRFs.

Condition
Paroxysmal Nocturnal Hemoglobinuria
Overall Status
Recruiting
Number of Participants
100
Start Date
Sep 19, 2024
Completion Date
Sep 30, 2028
Gender
All
Age(s)
0 Years - 100 Years (Child, Adult, Older Adult)

Eligibility Criteria

Inclusion Criteria:

All patients who received Fabhalta.

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Exclusion Criteria:

Patients receiving Fabhalta for an unapproved indication under the Clinical Trials Act or GCP.

Japan

Novartis Investigative Site

Recruiting

Toyota,Aichi,471-8513,Japan

Novartis Investigative Site

Recruiting

Kobe,Hyogo,650-0047,Japan

Novartis Investigative Site

Recruiting

Kanoya,Kagoshima,893-0024,Japan

Novartis Investigative Site

Recruiting

Isehara,Kanagawa,259-1193,Japan

Novartis Investigative Site

Recruiting

Habikino City,Osaka,583-0872,Japan

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Recruiting

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Novartis Investigative Site

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Osaka,542-0081,Japan

Novartis Investigative Site

Recruiting

Okazaki,Aichi,444-8553,Japan

Worldwide Contacts

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

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06606314*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT06606314
2. #trial-eligibility
3. tel:+81337978748
4. mailto:novartis.email@novartis.com