Entresto Tablets and Granules for Pediatric Specified Drug-use Survey (Pediatric Chronic Heart Failure)

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Entresto Tablets and Granules for Pediatric Specified Drug-use Survey (Pediatric Chronic Heart Failure, CLCZ696F1401)
ClinicalTrials.gov Identifier:
NCT06659393
Novartis Reference Number:CLCZ696F1401
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 multicenter, single-arm, non-interventional, centrally enrolled specified drug-use survey to investigate the safety of Entresto Tablets or Entresto Granules for Pediatric in pediatric patients with chronic heart failure in actual clinical settings for up to 52 weeks after administration. This specified drug-use survey is conducted to collect information on the safety specifications of Entresto in pediatric patients with chronic heart failure in Japan in actual clinical settings, and to investigate the occurrence of events related to the safety specifications, the risk factors associated with these events, and the status of Entresto administration including the accidental administration of capsule-shaped container (Granules for Pediatric). The subjects of this study are pediatric patients and a long-term observation of 1 year (52 weeks) has been set.

Condition
Pediatric Chronic Heart Failure
Overall Status
Recruiting
Number of Participants
33
Start Date
Dec 19, 2024
Completion Date
Nov 30, 2027
Gender
All
Age(s)
1 Year - 17 Years (Child)

Eligibility Criteria

Inclusion criteria

1. Written informed consent by a legally acceptable representative must be obtained before the start of treatment with Entresto.
2. Patients who received Entresto for the first time under the indication of chronic heart failure
3. Pediatric patients aged 1 to \< 18 years old at the start of treatment with Entresto

Exclusion criteria

1. Patients who have received drugs containing the same ingredient as Entresto (including investigational products and drugs for post-marketing clinical study)
2. Patients for whom Entresto is contraindicated according to the package insert

* Patients with a history of hypersensitivity to any ingredients of Entresto
* Patients currently under treatment with angiotensin-converting enzyme inhibitors or within 36 hours of discontinuation of treatment with angiotensin-converting enzyme inhibitors (alacepril, imidapril hydrochloride, enalapril maleate, captopril, quinapril hydrochloride, cilazapril hydrate, temocapril hydrochloride, delapril hydrochloride, trandolapril, benazepril hydrochloride, perindopril erbumine, lisinopril hydrate).
* Patients with a history of angioedema (including angioedema due to angiotensin II receptor blockers or angiotensin-converting enzyme inhibitors, hereditary angioedema, acquired angioedema, and idiopathic angioedema etc.)
* Patients with diabetes mellitus under treatment with aliskiren fumarate (excluding patients with markedly poorly controlled blood pressure despite other antihypertensive therapies)
* Patients with severe hepatic impairment (Child-Pugh class C)
* Pregnant women or women who may be pregnant

Japan

Novartis Investigative Site

Recruiting

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Recruiting

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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/nct06659393*

List of links present in page

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2. #trial-eligibility
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