

Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of LCZ696 Followed by a 52-week Study of LCZ696 Compared With Enalapril in Pediatric Patients With Heart Failure- PANORAMA

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Main Information

Primary registry identifying number

LBCTR2019040224

Protocol number

CLCZ696B2319

MOH registration number

22659/2018

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Retrospective

Type of registration: Justify

LCTR was recently initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency

29/05/2018

Primary sponsor

Novartis Pharma Services Inc.

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in primary registry

29/06/2022

Date of registration in national regulatory agency

29/05/2018

Public title

Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of LCZ696 Followed by a 52-week Study of LCZ696 Compared With Enalapril in Pediatric Patients With Heart Failure- PANORAMA

Acronym

PANORAMA

Scientific title

Multicenter, Open-label Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of LCZ696 Followed by a 52-week Randomized, Double-blind, Parallel Group, Active-controlled Study to Evaluate the Efficacy and Safety of LCZ696 Compared With Enalapril in Pediatric Patients From 1 Month to < 18 Years of Age With Heart Failure Due to Systemic Left Ventricle Systolic Dysfunction

Acronym

Brief summary of the study: English

This study consist of two parts (Part 1 and Part 2). The purpose of Part 1 is to evaluate the way the body absorbs, distributes and removes the drug LCZ696. This will help determine the proper dose of LCZ696 for Part 2 of the study.

The purpose for Part 2 is to compare the effectiveness and safety of LCZ696 with enalapril in pediatric heart failure patients over 52 weeks of treatment.

Brief summary of the study: Arabic



52تليها دراسة لمدة LCZ696 دراسة متعددة المراكز، مفتوحة العنوان؛ لتقييم الأمان والتحمل والحركيات الدوائية والديناميكيات الدوائية لعقار مقارنة بعقار LCZ696 أسبوعاً عشوائية، مزدوجة التعمية، من مجموعات علاج متوازنة، مضبوطة بعقار فعّال، ؛ لتقييم أمان وفعالية عقار سنة و يعانون من فشل القلب بسبب قصور جهازي بوظائف 18إنالابريل في الأطفال المرضى الذين تتراوح أعمارهم بين شهر واحد إلى أقل من انقباض البطين الأيسر

Health conditions/problem studied: Specify

Cardiovascular / Pediatric Heart Failure

Interventions: Specify

Drug: LCZ696

LCZ696: 3.125 mg granules (packaged in capsules containing 4 or 10 granules), 50 mg, 100 mg, 200 mg dosage strengths

Drug: Enalapril

Enalapril will be open label in Part 1 and double blind in Part 2

Drug: Placebo of LCZ696

Drug: Placebo of Enalapril

Key inclusion and exclusion criteria: Inclusion criteria

Chronic heart failure resulting from left ventricular systolic dysfunction, and receiving chronic HF therapy (if not newly diagnosed)

NYHA classification II-IV (older children: 6 to <18 years old) or Ross CHF classification II-IV (younger children: < 6 years old)

Systemic left ventricular ejection fraction $\leq 40\%$ or fractional shortening $\leq 20\%$

For Part 1 study: Patients must be treated with an ACEI or ARB prior to screening. Patients in Group 1 and 2 must be currently treated with the dose equivalent of at least enalapril 0.2 mg/kg prior to the LCZ696 3.1 mg/kg administration. Group 3 patients will participate in LCZ696 0.8 mg/kg and not LCZ696 3.1 mg/kg.

Biventricular physiology with systemic left ventricle

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

1

Key inclusion and exclusion criteria: Age maximum

17

Key inclusion and exclusion criteria: Exclusion criteria

Patient with single ventricle or systemic right ventricle

Patients listed for heart transplantation (as United Network for Organ Sharing status 1A) or hospitalized waiting for transplant (while on inotropes or with ventricular assist device)

Sustained or symptomatic dysrhythmias uncontrolled with drug or device therapy

Patients that have had cardiovascular surgery or percutaneous intervention to palliate or correct congenital cardiovascular malformations within 3 months of the screening visit. Patients anticipated to undergo corrective heart surgery during the 12 months after entry into Part 2

Patients with unoperated obstructive or severe regurgitant valvular (aortic, pulmonary, or tricuspid) disease, or significant systemic ventricular outflow obstruction or aortic arch obstruction

Patients with restrictive or hypertrophic cardiomyopathy

Active myocarditis

Renal vascular hypertension (including renal artery stenosis)

Moderate-to severe obstructive pulmonary disease

Serum potassium > 5.3 mmol/L

History of angioedema

Allergy or hypersensitivity to ACEI / ARB

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Active

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

IMP has market authorization

Yes, Lebanon and Worldwide

Name of IMP

LCZ696 Entresto

Type of IMP

Others

Pharmaceutical class

angiotensin receptor neprilysin inhibitor

Therapeutic indication

Chronic Heart Failure

Therapeutic benefit

Global Rank endpoint through 52 weeks of Treatment

Study model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration
Number of groups/cohorts
Biospecimen retention

Samples without DNA

Target sample size

10

Date of first enrollment: Type

Actual

Study design: Specify assignment

N/A

IMP has market authorization: Specify

Approved for Adults use only : France, Germany, Belgium, UK, USA, KSA, UAE, Turkey

Year of authorization

2016

Month of authorization

3

Study model: Explain model

N/A

Time perspective: Explain time perspective

N/A

Target follow-up duration: Unit
Biospecimen description

Biological samples : Urine, Hematology, Chemistry will be sent to Clinical Reference Laboratory, Europe Ltd.
7310 Cambridge Research Park
Beach Drive, Waterbeach
Cambridge, CB25 9TN
United Kingdom

Actual enrollment target size

10

Date of first enrollment: Date

17/08/2018

**Date of study closure: Type**

Actual

Date of study closure: Date

28/02/2022

Recruitment status

Complete

Recruitment status: Specify**Date of completion**

11/12/2020

IPD sharing statement plan

No

IPD sharing statement description

Not provided

Additional data URL

<https://clinicaltrials.gov/ct2/show/record/NCT02678312?term=pediatric&cond=Cardiovascular+Diseases&cntry=LB&rank=1>

Admin comments**Trial status**

Approved

Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| Clinicaltrials.gov | NCT02678312 |

Sources of Monetary or Material Support

| Name |
|-------------------------------|
| Novartis Pharma Services Inc. |

Secondary Sponsors

| Name |
|------|
| NA |



Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|--------------|-------------------|------------|---------|------------------------|-------------------------------|----------------------------------|
| Public | Ghassan Chehab | Beirut | Lebanon | 009613388581 | ghassanchehab@yahoo.com | Rafik Hariri University Hospital |
| Scientific | Hind Khairallah | Sin El Fil | Lebanon | +961 1 512002 Ext. 271 | Hind.Khairallah@fattal.com.lb | Khalil Fattal et Fils s.a.l. |
| Public | Linda Daou | Beirut | Lebanon | 009613524424 | drindadaou@gmail.com | Hotel Dieu De France |

Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|----------------------------------|---------------------------------|------------------------------------|------------------|
| Hotel Dieu De France | Dr Linda Daou | Pediatric Cardiologist | Approved |
| Rafik Hariri University Hospital | Dr Ghassan Chehab | Pediatric Cardiologist | Approved |

Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|----------------------------------|---------------|--------------|--------------------------|--------------------|
| Hotel Dieu de France | 27/02/2018 | Sami Richa | cue@usj.edu.lb | 961421229 |
| Rafic Hariri University Hospital | 09/01/2018 | Rawan Yamout | rawan.yamout@crurhuh.com | 018300000 ext 2037 |



Countries of Recruitment

| Name |
|--------------------------|
| Lebanon |
| Argentina |
| Bulgaria |
| Canada |
| China |
| Croatia |
| Finland |
| France |
| Hungary |
| Japan |
| Jordan |
| Turkey |
| United States of America |

Health Conditions or Problems Studied

| Condition | Code | Keyword |
|---------------|------------------------------------|---------|
| Heart Failure | Heart failure, unspecified (I50.9) | HF |

Interventions

| Intervention | Description | Keyword |
|--|--|--------------------------|
| Physical Exam, Vital signs, ECG, Echocardiography, Urinalysis, Serum/ urine pregnancy test, lab test, completion of QoL questionnaires | Physical Exam, Vital signs, ECG, Echocardiography, Urinalysis, Serum/ urine pregnancy test, lab test, completion of QoL questionnaires | ICF, Lab, IMP, radiology |



Primary Outcomes

| Name | Time Points | Measure |
|--|-------------|----------|
| Percentage of patients falling into each category based on global ranking | 52 weeks | 52 weeks |
| The global ranking is based on clinical events such as death, listing for urgent heart transplant, mechanical life support requirement at end of study, worsening heart failure (HF), New York Heart Association (NYHA)/Ross, Patient Global Impression of Severity (PGIS), Pediatric Quality of Life Inventory (PedsQL) physical functioning domain. The primary endpoint will be derived based on 5 categories ranking worst to best outcome | 52 weeks | 52 weeks |

Key Secondary Outcomes

| Name | Time Points | Measure |
|--|-------------|----------|
| Time to first occurrence of Category 1 or Category 2 event | 52 weeks | 52 weeks |
| Change from baseline in NYHA/Ross functional class | 52 weeks | 52 weeks |



Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files