THETIS- Efficacy and Safety Study of Deferasirox in Patients With Non-transfusion Dependent Thalassemia

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Main Information

Primary registry identifying number
LBCTR2020011375

Protocol number
CICL670E2419

MOH registration number
9932/ص

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
Study was submitted previously before implementation of LBCTR

Date of registration in national regulatory agency
03/11/2014

Primary sponsor
Novartis Pharmaceuticals

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
07/01/2020

Date of registration in national regulatory agency
03/11/2014

Public title
THETIS- Efficacy and Safety Study of Deferasirox in Patients With Non-transfusion Dependent Thalassemia

Acronym

Scientific title
An Open Label, Multi-center, Efficacy and Safety Study of Deferasirox in Iron Overloaded Patients With Non-transfusion Dependent Thalassemia

Acronym

Brief summary of the study: English
Assessed the efficacy of deferasirox in patients with non-transfusion dependent thalassemia based on change in liver iron concentration from baseline after 52 weeks of treatment. Provided further assessment of the long-term efficacy and safety of deferasirox in NTDT patients with iron overload (LIC ≥ 5 mg Fe/g liver dw and SF ≥ 300 ng/mL) for up to 260 weeks.

Brief summary of the study: Arabic
دراسة مفتوحة اللصاقة متعدّدة المراكز حول فعالية وسلامة دواء ديفيرازيروكس لدى مرضى التالاسيميا غير المعتمدين على نقل الدم الذين يعانون من زيادة تركيز الحديد (THETIS)

Health conditions/problem studied: Specify
Non-transfusion Dependent Thalassemia

Interventions: Specify
Drug: deferasirox
Deferasirox dispersible tablets at strengths of 125 mg, 250 mg, and 500 mg were administered by oral daily dosing.

Other Name: ICL670

Key inclusion and exclusion criteria: Inclusion criteria
Non-transfusion dependent congenital or chronic anemia inclusive of beta-thalassemia intermedia, HbE beta-thalassemia or alpha-thalassemia

intermedia (HbH disease)/ Liver iron concentration >/= 5 mg Fe/g dw Serum Ferritin >/= 300 ng/mL

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

10

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

HbS-beta Thalassemia, anticipated regular transfusion program during the study, blood transfusion 6 months prior to study start, significant proteinuria..

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

N/A: Single arm study

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

4

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

China, Greece, Italy, Lebanon, Thailand, Tunisia, Turkey, United Kingdom

Name of IMP

Deferasirox (ICL670)

Year of authorization

2006

Month of authorization

4

Type of IMP

Others

Pharmaceutical class

Iron chelator

Therapeutic indication

Thalassemia

Therapeutic benefit

Change in liver iron concentration

Study model

N/A

Study model: Explain model

Study model: Specify model

N/A

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples without DNA

Biospecimen description

Samples are sent to central lab for analysis

Target sample size

20

Actual enrollment target size

20

Date of first enrollment: Type

Actual

Date of first enrollment: Date

26/02/2013

Date of study closure: Type

Actual

Date of study closure: Date

17/01/2019

Recruitment status

Complete

Recruitment status: Specify

Date of completion

31/12/2013

IPD sharing statement plan

Yes

IPD sharing statement description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent expert panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data is currently available according to the process described on www.clinicalstudydatarequest.com.

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT01709838?view=record

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
clinicaltrials.gov	NCT01709838

Sources of Monetary or Material Support

Name
Novartis Pharmaceuticals

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Ali Taher	Beirut	Lebanon	01350000#7908	ataher@aub.edu.lb	Chronic Care Center
Scientific	Hind Khairallah	Sin elfil	Lebanon	+961 1512002 #271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Chronic Care Center	Ali Taher	Hematology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Chronic Care Center	17/11/2012	Michele Abi saad	cccmas@chroniccare.org.lb	+961 3 664 310
American University of Beirut Medical Center	30/11/2012	Fuad Ziyadeh	fz05@aub.edu.lb	961 (0) 1 350 000 ext:5445

Countries of Recruitment

Name
Lebanon
China
Greece
Italy
Thailand
Tunisia
Turkey

Health Conditions or Problems Studied

Condition	Code	Keyword
Non-transfusion Dependent Thalassemia	Thalassaemia, unspecified (D56.9)	Non-transfusion Dependent Thalassemia

Interventions

Intervention	Description	Keyword
ICF, Labs, drug administraion , Radiology	ICF, Labs, drug administraion , Radiology	ICF, Labs, drug administraion , Radiology

Primary Outcomes

Name	Time Points	Measure
Absolute change in liver iron concentration measured by MRI	baseline, 52 weeks	baseline, 52 weeks

Key Secondary Outcomes

Name	Time Points	Measure
•Percentage of Participants With Baseline LIC more than 15 Achieving LIC less than 5 mg	5 years	5 years
•Time to Achieving LIC less than 5 mg	5 years	5 years

Trial Results

Summary results

Study results globally

https://clinicaltrials.gov/ct2/show/results/NCT01709838?view=results

Reference study results tab in the above link of clinical trials.gov

Date of posting of results summaries

Date of first journal publication of results

Results URL link

https://clinicaltrials.gov/ct2/show/results/NCT01709838?view=results

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files