



Rollover Study for Patients With Sickle Cell Disease Who Have Completed a Prior Novartis-Sponsored Crizanlizumab Study

11/04/2025 08:13:34

Main Information

Primary registry identifying number

LBCTR2021104867

Protocol number

CSEG101A2401B

MOH registration number

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Prospective

Type of registration: Justify

N/A

Date of registration in national regulatory agency

Primary sponsor

Novartis Pharmaceuticals

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in primary registry

18/07/2024

Date of registration in national regulatory agency

Public title

Rollover Study for Patients With Sickle Cell Disease Who Have Completed a Prior Novartis-Sponsored Crizanlizumab Study

Acronym

Scientific title

An Open-label, Multi-center, Phase IV, Rollover Study for Patients With Sickle Cell Disease Who Have Completed a Prior Novartis-Sponsored Crizanlizumab Study

Acronym

Brief summary of the study: English

This is a multi-center multi-national rollover study to allow continued access to crizanlizumab for patients with sickle cell disease (SCD) who are on crizanlizumab treatment in a Novartis-sponsored study (parent study) and are benefiting from the treatment as judged by the investigator.

Brief summary of the study: Arabic

دراسة تمديد مفتوحة التسمية، متعددة المراكز، في المرحلة الرابعة لمرضى مصابين بداء الكريات المنجلية أنجزوا دراسة سابقة حول كريسز الليزوماب برعاية نوفارتيس

Health conditions/problem studied: Specify

Sickle Cell Disease

Interventions: Specify

Drug: Crizanlizumab
Concentrate for solution for infusion for Intravenous use
Other Name: SEG101

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion criteria:

1. Written informed consent/assent, according to local guidelines, signed by the adult patients. In the population under 18 years, it will be signed by the patient and/or by the parents or legal guardian prior to enrolling in the rollover study and receiving study medication





2.SCD patient currently enrolled in a Novartis-sponsored study receiving crizanlizumab and has fulfilled all the requirements in the parent study. Patient is currently benefiting from the treatment with crizanlizumab as determined by the investigator and has completed the treatment schedule as planned in the parent study

3.Patient has demonstrated compliance to the planned visit schedule in the parent study, and in the opinion of the investigator has shown willingness and ability to comply with future visit schedules

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

6

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

- 1.Patient had permanently discontinued from crizanlizumab study treatment in the parent study before the parent study completion
- 2.Ongoing/unresolved treatment-related Grade 3 or higher AEs, and/or any ongoing AE requiring dose interruption. Patients meeting all other eligibility criteria may be enrolled once toxicities have resolved unless those toxicities were grade 4
- 3.Concurrent participation in any other investigational clinical trial other than the parent study or plan to participate in any other investigational clinical trial
- 4.Pregnant or nursing women
- 5.Women of childbearing potential who are unwilling to be on highly effective contraceptives during dosing and until 15 weeks after stopping treatment with crizanlizumab
- 6.SCD patients who do not meet parent study protocol criteria to continue with crizanlizumab

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

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

Albania,Australia,Austria,Bahrain,Belgium,Brazil,Bulgaria, Lebanon,United Arab Emirates, United Kingdom, United States,South Africa,Norway, Oman, Qatar, Romania Denmark, Germany, Greece,Italy,France.

Name of IMP

Crizanlizumab

Year of authorization

2020

Month of authorization

12

Type of IMP

Others

Pharmaceutical class

anti-P-selectin

Therapeutic indication

Sickle Cell Disease

**Therapeutic benefit**

Not Applicable as this protocol is to provide an option for continued access to crizanlizumab for patients with Sickle Cell Disease who have completed a prior Novartis-sponsored Crizanlizumab study

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

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**

None retained

Biospecimen description

N/A

Target sample size

10

Actual enrollment target size

8

Date of first enrollment: Type

Actual

Date of first enrollment: Date

29/12/2021

Date of study closure: Type

Actual

Date of study closure: Date

17/01/2029

Recruitment status

Recruiting

Recruitment status: Specify**Date of completion**

31/10/2025

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/NCT04657822?term=CSEG101A2401B&draw=2&rank=1>

Admin comments**Trial status**

Approved

Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| Clinicaltrials.gov | NCT04657822 |

Sources of Monetary or Material Support

| Name |
|-------------------------------|
| Novartis pharma services Inc. |

Secondary Sponsors

| Name |
|------|
| N/A |

Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|--------------|-------------------|--|---------|-------------------|-------------------------------|--|
| Public | Adlette Inati | Tripoli | Lebanon | 961 (0) 3 228 033 | adlette.inati@lau.edu.lb | Nini Hospital |
| Scientific | Hind Khairallah | KFF Healthcare - Khalil Fattal et fils | Lebanon | +961 1512002 #271 | Hind.Khairallah@fattal.com.lb | Khalil Fattal et Fils Sal |
| Public | Miguel Abboud | Beirut | Lebanon | 961353421 3 | ma56@aub.edu.lb | American University of Beirut Medical Center |



Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|--|---------------------------------|------------------------------------|------------------|
| Nini Hospital | Adlette Inati | Pediatric Hematology | Approved |
| American University of Beirut Medical Center | Miguel Abboud | Pediatric Hematology | Approved |

Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|--|---------------|---------------|-------------------------------|-----------------------------|
| Nini Hospital | 08/10/2021 | Nabil Kabbara | Nabil.kabbara@hopitalnini.com | +961 (0) 6 431 400 ext 1062 |
| American University of Beirut Medical Center | 14/12/2021 | Fuad Ziyadeh | fz05@aub.edu.lb | 961 (0) 1 350 000 ext:5445 |

Countries of Recruitment

| Name |
|---------|
| Lebanon |
| Belgium |

Health Conditions or Problems Studied

| Condition | Code | Keyword |
|---------------------|-----------------------------|---------|
| sickle cell disease | Sickle-cell disorders (D57) | SCD |

Interventions

| Intervention | Description | Keyword |
|--------------------------------|--------------------------------|--------------------------------|
| Consenting, IMP administration | Consenting, IMP administration | Consenting, IMP administration |

Primary Outcomes

| Name | Time Points | Measure |
|---|-----------------------------------|-----------------------------------|
| Not Applicable as this protocol is to provide an option for continued access to crizanlizumab for patients with Sickle Cell Disease who have completed a prior Novartis-sponsored Crizanlizumab study | Not Applicable - Study Completion | Not Applicable - Study Completion |



Key Secondary Outcomes

| Name | Time Points | Measure |
|---|--|--|
| Number of participants with treatment emergent adverse events | from day of first dose of study medication to 105 days after last dose of study medication | from day of first dose of study medication to 105 days after last dose of study medication |

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