



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

22/11/2024 04:40:21

## 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**

13/02/2023

**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 اليليزوماب 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**

5

**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**

31/03/2023

**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](http://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	9613534213	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**