



# SEG101A2203 Study Exploring the Effect of Crizanlizumab on Kidney Function in Patients With Chronic Kidney Disease Caused by Sickle Cell Disease

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## Main Information

**Primary registry identifying number**

LBCTR2020094586

**Protocol number**

SEG101A2203

**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**

02/10/2020

**Date of registration in national regulatory agency**

**Public title**

SEG101A2203 Study Exploring the Effect of Crizanlizumab on Kidney Function in Patients With Chronic Kidney Disease Caused by Sickle Cell Disease

**Acronym**

SEG101A2203 STEADFAST

**Scientific title**

A Phase II, Multicenter, Randomized, Open Label Two Arm Study Comparing the Effect of Crizanlizumab + Standard of Care to Standard of Care Alone on Renal Function in Sickle Cell Disease Patients  $\geq$  16 Years With Chronic Kidney Disease Due to Sickle Cell Nephropathy

**Acronym**

**Brief summary of the study: English**

The goal of the study is to compare the efficacy and safety of crizanlizumab + standard of care to standard of care alone on renal function in sickle cell disease patients  $\geq$  16 years with chronic kidney disease due to sickle cell nephropathy.

**Brief summary of the study: Arabic**

دراسة مرحلة ثانية، متعددة المراكز، عشوائية التوزيع، مفتوحة اللصاق، من مجموعتين لمقارنة تأثير كريزانليزوماب + الرعاية المعتمدة سنة المصابين بمرض كلوي مزمن ناتج عن اعتلال 16 بالرعاية المعتمدة لوحدها، على الوظيفة الكلوية لدى مرضى داء الكريات المنجلية  $\leq$  (STEADFAST) الكلية المنجلية

**Health conditions/problem studied: Specify**

Sickle Cell Disease (SCD)

**Interventions: Specify**

Drug: Crizanlizumab (SEG101)



**Key inclusion and exclusion criteria: Inclusion criteria**

- Confirmed diagnosis of SCD (HbSS and HbS $\beta$ 0-thal SCD genotypes are eligible)
- Patients with eGFR  $\geq$  45 to  $\leq$  120 mL/min/1.73 m<sup>2</sup> based on CKD EPI formula
  - Patients with ACR of  $\geq$  100 to  $<$  2000 mg/g
  - Receiving standard of care drug(s) for SCD and/or CKD for at least 6 months prior to study entry
  - Hb  $\geq$  4.0 g/dL, absolute neutrophil count (ANC)  $\geq$  1.0 x 10<sup>9</sup>/L, and platelet count  $\geq$  75 x 10<sup>9</sup>/L
  - Written informed consent (or assent/ parental consent for minor subjects) prior to any screening procedures

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender****Key inclusion and exclusion criteria: Age minimum**

16

**Key inclusion and exclusion criteria: Age maximum**

99

**Key inclusion and exclusion criteria: Exclusion criteria**

- History of stem cell transplant
- Patients with evidence of AKI within 3 months of study entry
  - Blood pressure  $>$  140/90 mmHg despite treatment
  - Patients undergoing hemodialysis
  - Received blood products within 30 days of Week 1 Day 1
  - Participating in a chronic transfusion program
  - History of kidney transplant
  - Patients with hypoalbuminemia

**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**

Open (masking not used)

**Study design: Control**

N/A

**Study phase**

2

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization**

Yes, Worldwide

**IMP has market authorization: Specify**

US, albania, bahrain, brazil, india , UAE

**Name of IMP**

Crizanlizumab

**Year of authorization****Month of authorization****Type of IMP**

Immunological

**Pharmaceutical class**

Crizanlizumab is a concentrate for solution for infusion, i.v. use. Supplied in single use 10 mL vials at a concentration of 10 mg/mL. One vial contains 100 mg of crizanlizumab  
Other Name: SEG101

**Therapeutic indication**



Patients with:  
Sickle cell diseases

**Therapeutic benefit**

Percentage of patients with  $\geq 30\%$  decrease in albuminuria (ACR) [ Time Frame: Baseline to 12 months ]

To evaluate the effect of crizanlizumab + standard of care compared to standard of care alone on albuminuria (ACR) decrease

**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**

Samples without DNA

**Biospecimen description**

Samples will be sent to Covance central lab

**Target sample size**

5

**Actual enrollment target size**

**Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

29/10/2020

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

29/08/2023

**Recruitment status**

Pending

**Recruitment status: Specify**

**Date of completion**

28/10/2021

**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/NCT04053764?term=CSEG101A2203&draw=2&rank=1>

**Admin comments****Trial status**

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
clinical trials.gov	NCT04053764

## 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	Adlette Inati	Tripoli	Lebanon	9613228033	adlette.inati@lau.edu.lb	Nini Hospital
Scientific	Hind Khairallah	Beirut	Lebanon	9611512002	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils



## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Nini Hospital	Adlette Inati	Hematology	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Nini Hospital	17/08/2020	Nabil Kabbara	Nabil.kabbara@hopitalnini.com	961 (0) 6 431 400 ext 1062

## Countries of Recruitment

Name
Lebanon
Brazil
France
Greece
Netherlands
Spain
Turkey

## Health Conditions or Problems Studied

Condition	Code	Keyword
Sickle cell	Sickle-cell disorders (D57)	SCD

## Interventions

Intervention	Description	Keyword
ICF-Labs-IMP administration-Questionnaires	ICF-Labs-IMP administration-Questionnaires	ICF-Labs-IMP administration-Questionnaires



## Primary Outcomes

Name	Time Points	Measure
To evaluate the effect of crizanlizumab + standard of care compared to standard of care alone on albuminuria (ACR) decrease	12 months	12 Months

## Key Secondary Outcomes

Name	Time Points	Measure
Mean change in albuminuria (ACR)	3,6,9,12 months	3,6,9,12 months
Percentage of patients with $\geq 30\%$ decrease in albuminuria (ACR)	Baseline to 6 months	Baseline to 6 months
Percentage of patients with $\geq 20\%$ improvement of protein to creatinine ratio (PCR)	Baseline to 12 months	Baseline to 12 months
Percentage of patients with a stable (within $\pm 20\%$ change) protein to creatinine ratio (PCR)	Baseline to 12 months	Baseline to 12 months
Percentage change in estimated glomerular filtration rate (eGFR)	Baseline to 3, 6, 9 and 12 months	Baseline to 3, 6, 9 and 12 months
Slope of albumin to creatinine ratio (ACR) decline	Baseline, 3, 6, 9, and 12 months	Baseline, 3, 6, 9, and 12 months
Slope of estimated glomerular filtration rate (eGFR) decline	Baseline to 3, 6, 9 and 12 months	Baseline to 3, 6, 9 and 12 months
Percentage of patients with progression of chronic kidney disease (CKD)	Baseline to 12 months	Baseline to 12 months
Immunogenicity: measurement of anti-drug antibodies (ADA) to crizanlizumab	Baseline to follow-up period	Baseline to follow-up period
Annualized rate of visits to emergency room and hospitalizations	Baseline to follow-up period	Baseline to follow-up period



## 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**