



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

29/05/2021

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 سنة المصابين بمرض كلوي مزمن ناتج عن اعتلال 16 بالرعاية المعتمدة لوحدها، على الوظيفة الكلوية لدى مرضى داء الكريات المنجلية (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 β 0-thal SCD genotypes are eligible)
- Patients with eGFR \geq 45 to \leq 120 mL/min/1.73 m² 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 10⁹/L, and platelet count \geq 75 x 10⁹/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.

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