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 ≥ 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 ≥ 16 years with chronic kidney disease due to sickle cell nephropathy.

Brief summary of the study: Arabic
دراسة مرحلة ثانية، متعددة المراكز، عشوائيّة التوزيع، مفتوحة اللصاقة، من مجموعتين لمقارنة تأثير كريزانليزوماب + الرعاية المعتمدة بالرعاية المعتمدة لوحدها، على الوظيفة الكلويّة لدى مرضى داء الكريات المنجليّة ≤ سنة المصابين بمرض كلويّ مزمن ناتج عن اعتلال16 الكلية المنجلي (STEADFAST)

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 HbSβ0-thal SCD genotypes are eligible)
- Patients with eGFR ≥ 45 to ≤ 120 mL/min/1.73 m2 based on CKD EPI formula
- Patients with ACR of ≥ 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 ≥ 4.0 g/dL, absolute neutrophil count (ANC) ≥ 1.0 x 109/L, and platelet count ≥ 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 diseas

Therapeutic benefit

Percentage of patients with ≥ 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	96115120002	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 ≥ 30% decrease in albuminuria (ACR)	Baseline to 6 months	Baseline to 6 months
Percentage of patients with ≥ 20% improvement of protein to creatinine ratio (PCR)	Baseline to 12 months	Baseline to 12 months
Percentage of patients with a stable (within ± 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