This document provides a short summary of this study for a general audience. You can find more information in the scientific summary of the study. A link to the summary is provided at the end of this document.

Study names

Short Title: A study to learn about the effect of daprodustat on blood pressure in patients with anaemia due to chronic kidney disease.

Full Scientific Title: A randomised, open label study to evaluate the effect of daprodustat on blood pressure in subjects with anaemia associated with chronic kidney disease on haemodialysis switched from a stable dose of an erythropoiesis-stimulating agent.

Study Number: 205665

Who sponsored this study?

GlaxoSmithKline (GSK)
GSK Clinical Support Help Desk
Website: clinicalsupporthd.gsk.com/contact.html
Email: GSKClinicalSupportHD@gsk.com

General information about the clinical study

When and where was this study done?

The study started in July 2017 and ended in July 2020. All study sites were in the United States.

What was the main reason for this study?

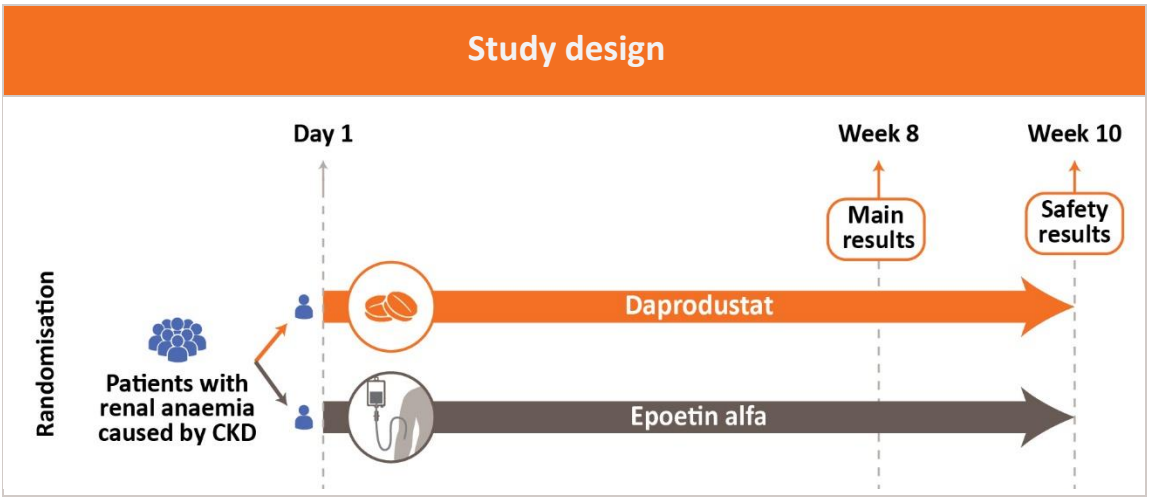
Chronic kidney disease (CKD) is a long-term disease of the kidneys. Some people with CKD cannot make enough of a protein that carries oxygen in the blood (haemoglobin). This condition is called renal anaemia.

Patients with renal anaemia may be treated with erythropoiesis-stimulating agents (ESAs), such as epoetin alfa. These agents may increase blood pressure in patients with renal anaemia. Daprodustat is a medicine that is being tested to treat renal anaemia.

Researchers wanted to see how well daprodustat works in maintaining blood pressure compared with epoetin alfa in patients with renal anaemia. Researchers also assessed the safety of these medicines.

Which medicines were studied?

On Day 1, patients were included in one of the two treatment groups by chance (randomisation), as shown in the figure below.



The patient and the study doctor knew which treatment the patient received.

Which patients were included in this study?

Studies have a list of requirements for patients who can enrol (inclusion criteria) and those who can't (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

Men and women with renal anaemia were included in the study if they:

- Were at least 40 years old.
- Had haemoglobin levels between 8.5 grams per decilitre (g/dL) and 11.5 g/dL before Day 1.
- Had haemodialysis (a treatment that filters blood and removes waste) three to five times a week for at least four weeks before starting the study.
- Had been taking an ESA for at least four weeks before starting the study.
- Were taking medicine(s) to control their blood pressure for at least one week before starting the study.

Men and women were excluded from the study if they had:

- A plan to change the type of dialysis during the study or were on home dialysis.
- A planned kidney transplant within 16 weeks of starting the study.
- Uncontrolled high blood pressure.
- A heart attack, stroke, or ministroke before Day 1.
- Another disease that could lead to anaemia.
- Stomach and intestinal bleeding before Day 1.
- Any other disease(s), abnormal blood test results, or taken any medicine(s), that the study doctor thought would affect the results of the study.

Overall, 88 patients received at least one dose of study medicine. The study included 53 men (60%) and 35 women (40%). The average age was 60 years. The youngest patient was 40 years old and the oldest patient was 84 years old.

For more detailed information about the patients included in this study, see the scientific results summary (a link to the summary is provided at the end of this document).

What were the main results of the study?

The main objective of the study was to compare daprodustat with epoetin alfa in maintaining patients' systolic blood pressure (SBP) after eight weeks (on Day 57). Systolic blood pressure is the pressure that blood exerts against the artery wall when the heart beats.

Study doctors measured each patient's blood pressure over six hours on Day 57. The average SBP was calculated for each treatment group.

The average SBP over six hours on Day 57 was 143 mmHg (millimetres of mercury) in the daprodustat group and the epoetin alfa group.

More information about the study results is available in the scientific results summary (a link to the summary is provided at the end of this document).

What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a medicine. Study doctors record these events. A summary of these events can be found in the scientific results summary (a link to the summary is provided at the end of this document).

If the study doctor thinks that the event was caused by the study medicine, they record this as a possible side effect (adverse reaction).

In this summary, side effects refer to those events that the study doctor thinks may have been caused by the study medicine. The side effects in this summary may be different to those in the Informed Consent or other documents related to the study medicine.

No serious side effects were reported during the study.

Non-serious side effects were reported by one patient (2%) in the daprodustat group and two patients (5%) in the epoetin alfa group. The table below shows the number of patients (percent) with non-serious side effects that were reported during this study.

Number of patients (percent) with non-serious side effects		
	Daprodustat 45 patients	**Epoetin alfa 43 patients**
Constipation	1 (2%)	0
Headache	0	2 (5%)
Diarrhoea	0	1 (2%)
High blood pressure	0	1 (2%)
Nausea	0	1 (2%)
Weakness	0	1 (2%)

How has this study helped patients and researchers?

Researchers did not see a difference between daprodustat and epoetin alfa in maintaining blood pressure in patients with renal anaemia. The non-serious side effects reported in this study were as expected.

Are there plans for further studies?

Other studies of daprodustat in patients with renal anaemia have been conducted and some are ongoing or planned.

Where can I find more information about this study?

Clinical studies have unique study numbers that are included in publications and other information about the study. The unique study number associated with this study is shown below with an internet link to the scientific summary.

The scientific summary includes more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events.

Organisation and Website	Study Number
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03029247[1]

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

We would like to thank the patients who contributed to this study. The results of this study will help answer scientific questions about treating patients with renal anaemia.

The content for this document was finalised by GSK on 27 May 2021. The information in this summary does not include additional information available after this date.

[1] https://clinicaltrials.gov/ct2/show/study/NCT03029247?term=NCT03029247&rank=1