This document provides a short summary of this study for a general audience. You can find more information in the scientific summaries of the study. Links to those summaries are provided at the end of this document.

Study names

Short Title: A study to learn about the effect of daprodustat on haemoglobin levels in participants with anaemia due to chronic kidney disease.

Full Scientific Title: A 52-week open label (sponsor-blind), randomised, active-controlled, parallel-group, multi-centre study to evaluate the efficacy and safety of daprodustat compared to recombinant human erythropoietin in subjects with anaemia associated with chronic kidney disease who are initiating dialysis.

Study Number: 201410

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 was this study done?

The study started in May 2017 and ended in September 2020.

What was the main objective of this study?

Chronic kidney disease (CKD) is a long-term disease of the kidneys. Some people with CKD cannot make enough red blood cells. This condition is called anaemia due to CKD. Red blood cells contain an oxygen-carrying protein called haemoglobin (Hgb). When people have anaemia, they have reduced amount of Hgb in their blood.

Patients with anaemia may be treated with erythropoiesis-stimulating agents (ESAs), such as darbepoetin alfa. These agents trigger the body to make more red blood cells, which leads to an increase in Hgb levels. There are other treatments in development that are being tested in clinical studies. Daprodustat is a medicine that is being tested to treat anaemia due to CKD.

Patients with anaemia due to CKD, who were on dialysis or planned to start dialysis, took part in this study. Dialysis is a treatment that removes waste from the body and filters blood when kidneys do not work well. Researchers wanted to see how well daprodustat works in increasing and maintaining Hgb levels compared with darbepoetin alfa in these participants. Researchers also assessed the safety of this medicine.

Which medicines were studied?

On Day 1 of the 52-week treatment period, participants were included in one of the following two treatment groups by chance (randomisation).

- Daprodustat: Participants received daprodustat tablets by mouth once daily.
- Darbepoetin alfa: Participants received darbepoetin alfa as an injection under the skin or through a vein once every two or four weeks.

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

Which participants were included in this study?

Studies have a list of requirements for participants 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 anaemia due to CKD were included in the study if they:

- Were 18 to 99 years old.
- Had Hgb levels between 8 grams per decilitre (g/dL) and 11 g/dL on Day 1.
- Had planned to start dialysis within six weeks of study start or had started dialysis no more than three months before Day 1.
- Were expected to receive dialysis for the duration of the study.

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

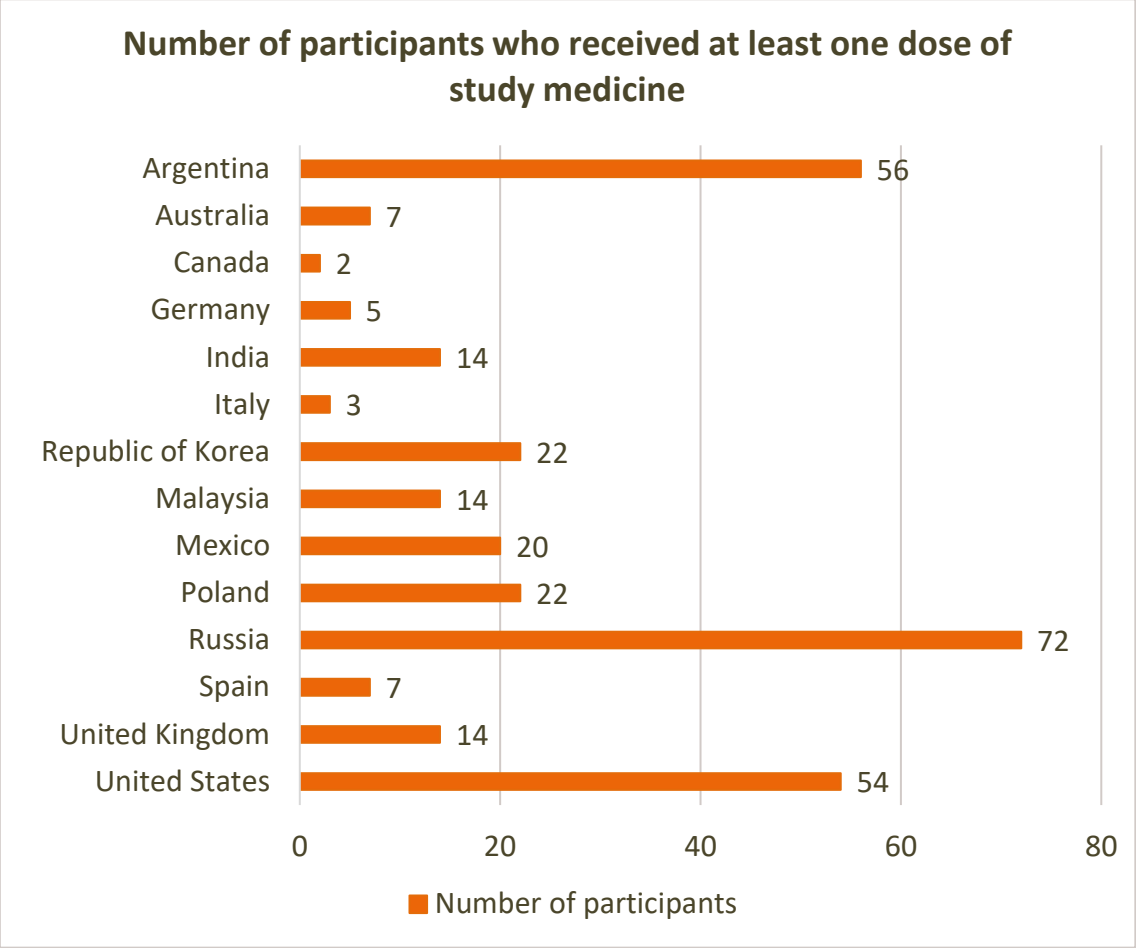
- A plan to have a kidney transplant during the study.
- Uncontrolled high blood pressure.
- A heart attack, stroke, or ministroke within three months before Day 1.
- Stomach and intestinal bleeding within three months before Day 1.
- Another disease that could lead to anaemia.
- Taken any ESA within two months before starting the study except when taken in limited doses.
- Any other disease(s), abnormal test results, or other medication use that would put the participant at unacceptable risk or affect the results of the study.

Overall, 312 participants received at least one dose of study medicine. The study included 194 men (62%) and 118 women (38%). The average age was 55 years. The youngest participant was 20 years old and the oldest participant was 86 years old.

For more detailed information about the participants included in this study, see the scientific results summaries (links to those summaries are provided at the end of this document).

Where was this study done?

Study sites were in 14 countries.



What were the main results of the study?

The main objective was to compare daprodustat with darbepoetin alfa in increasing and maintaining participants' Hgb levels during Week 28 to Week 52 (testing period) of the study.

Study doctors collected blood samples from the participants. They measured each participant's Hgb levels on Day 1 (baseline) and during the testing period. The difference in the participant's baseline Hgb value and the average Hgb value during the testing period was calculated. This is called the change from baseline for each participant.

The average change from baseline in Hgb levels was calculated for each treatment group. Results are shown in the table below.

Average change from baseline in Hgb levels during the testing period		
	Daprodustat 157 participants	**Darbepoetin alfa 155 participants**
Average change from baseline in Hgb levels	1.02 g/dL	1.12 g/dL

More information about the study results is available in the scientific results summaries (links to those summaries are 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 summaries (links to those summaries are 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.

The side effects in this summary have been reported for the 52-week treatment period.

Serious side effects

No serious side effect was reported in the daprodustat group. Two participants in the darbepoetin alfa group reported serious side effects. One participant had kidney cancer and the other participant had a blood clot formed at or near the dialysis site where two blood vessels were surgically connected.

Non-serious side effects

Non-serious side effects were reported by five participants (3%) each in the daprodustat group and the darbepoetin alfa group. Two participants (1%) in the daprodustat group had nausea. All the other non-serious side effects were reported by less than 1% of participants each in either treatment group.

How has this study helped participants and researchers?

Researchers concluded that daprodustat was similar to darbepoetin alfa in increasing and maintaining Hgb levels in participants with anaemia due to CKD. The side effects reported were as expected in patients with anaemia due to CKD.

Are there plans for further studies?

Other studies of daprodustat in participants with anaemia due to CKD have been completed 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 numbers associated with this study are shown below with internet links to scientific summaries.

The scientific summaries include 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
European Medicines Agency (www.clinicaltrialsregister.eu)	2016-000507-86[1]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03029208[2]

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-000507-86
[2] https://clinicaltrials.gov/ct2/show/NCT03029208

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 participants who contributed to this study. The results of this study will help answer scientific questions about treating patients with anaemia due to CKD.

The content for this document was finalised by GSK on 28 January 2022. The information in this summary does not include additional information available after this date.