

Summary of Results for Laypersons

Astellas is grateful to all who were involved in this study. Thank you.

What was the Study Called?

A Non-Interventional, Epidemiological, Registry-based Evaluation of Anaemia in Swedish Patients with Chronic Kidney Disease. This is also known as the ASK study.

Why was this Study Needed?

Healthy kidneys filter the blood. They also make a hormone called erythropoietin. This hormone tells the soft tissue within the bone (bone marrow) to make red blood cells. In chronic kidney disease, gradual lasting damage to the kidneys happens over time. The kidneys cannot filter the blood like they should. And they cannot make erythropoietin as they should. Therefore, patients with chronic kidney disease often have a lack of red blood cells (kidney anemia). Medicines called erythropoiesis-stimulating agents (ESAs for short) help replace what erythropoietin does. ESAs together with iron supplements can be used to treat kidney anemia. Iron can be taken by mouth (oral). Or it can be injected through a small needle placed in a vein in the arm (called intravenous). There is not yet enough information on iron supplements taken by patients with chronic kidney disease who take ESA medicines. Therefore, there was a need to study that.

What Kind of Study was this and Who Took Part in It?

This was a “registry-based” study. This means that researchers looked at information that had been reported to a medical database. Patients took their standard kidney medicines as prescribed by their doctors. Their doctors sent information about their treatment to a medical database. For this study, researchers looked at the information from the Swedish Renal Registry database. Researchers analyzed the information gathered from patients who were treated for kidney anemia in 2015 in Sweden. The sponsor of this study (Astellas) created a report of the results. This is a summary of the main analyses of that report.

Information was gathered from patients aged 18 or older. They had chronic kidney disease. The patients were being treated for a lack of red blood cells (kidney anemia). Some patients needed dialysis and others did not. Dialysis is a treatment to filter out wastes and extra salt and fluid from the blood.

The study took place in Sweden. Information was collected on 14415 patients. 11370 patients were not on dialysis and 3045 patients needed dialysis. 9636 patients had kidney anemia.

| | Number of Patients No Dialysis (out of 11370) | Number of Patients Dialysis (out of 3045) |
|------------------------------------|--|--|
| Age Group | | |
| Aged less than 65 years | 2922 (26%) | 1097 (36%) |
| Aged 65 to 79 years | 5406 (48%) | 1348 (44%) |
| 80 years or older | 3042 (27%) | 600 (20%) |
| Sex | | |
| Men | 7164 (63%) | 2052 (67%) |
| Women | 4206 (37%) | 993 (33%) |
| Patients with Kidney Anemia | 6792 (60%) | 2844 (93%) |

What Were the Study Results?

In the main analysis, researchers looked at the number of patients taking ESA medicines plus iron. They compared this to the total number of patients taking ESA (proportion). They compared patients who had dialysis and those without dialysis. They also looked at the type of iron used. Iron can be taken by mouth (oral). Or injected through a small needle placed in a vein in the arm (called intravenous).

Overall, the use of iron when taking ESA was lower than expected. Approximately 65% of patients on dialysis took iron. 40% of patients not on dialysis took iron. The proportions of usage increased with chronic kidney disease severity. Iron given through a vein in the arm was more common in dialysis patients. And iron taken by mouth was more common in patients not on dialysis.

Patients with ESA 5183

| No Dialysis 2692 | | Dialysis 2491 | |
|--|--|--|--|
| Iron Supplements 1074 (40%, 1074 out of 2692) | | Iron Supplements 1608 (65%, 1608 out of 2491) | |
| Oral Iron 667 (25%, 667 out of 2692) | Intravenous Iron 407 (15%, 407 out of 2692) | Oral Iron 83 (3%, 83 out of 2491) | Intravenous Iron 1525 (61%, 1525 out of 2491) |

Where Can I Learn More About This Study?

This document is a short summary of the main results from this study. You can find this summary and more information about this study online at <http://www.astellasclinicalstudyresults.com>.

Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. This summary only shows the results of this 1 study. Your doctor may help you understand more about the results of this study.

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