



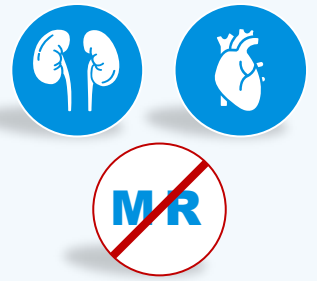
Summary of Research: Cardiovascular and Kidney Outcomes with Finerenone in Patients with Type 2 Diabetes and Chronic Kidney Disease— The FIDELITY Pooled Analysis



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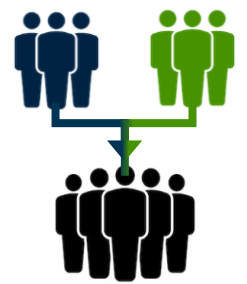
i Background

- If people with type 2 diabetes (T2D) develop chronic kidney disease (CKD), and their CKD becomes worse over time, their kidneys might stop working altogether. People with T2D and CKD are also at risk of developing heart disease and blood vessel disease
- Activity at the **mineralocorticoid receptor (MR)** can be increased. This leads to inflammation and scarring of the kidneys, heart and blood vessels
- **Finerenone** is a drug that blocks the MR. When the MR is blocked, activity at the MR is reduced.



Q Why was the analysis carried out?

- This analysis **combined the data** from two similar studies (FIDELIO-DKD and FIGARO-DKD) that looked at how safe and effective finerenone was at reducing kidney and heart problems in people with **T2D and CKD**
- By combining two large studies and analyzing the data, the researchers could get a **better picture** of how safe and how well finerenone works in a bigger group of people with **T2D and a broader range of CKD** (from mild to severe CKD)



Q Who could take part in this study? *Adults with T2D and CKD...*



- ✓ with an estimated glomerular filtration rate (eGFR) of at least 25 mL/min/1.73 m² of body surface area (eGFR is a measure that tells us how well the kidneys are working. Normal eGFR is 90 mL/min/1.73 m² of body surface area or more)
- ✓ with a urine albumin-to-creatinine ratio (UACR) of at least 30 mg/g (UACR is a measure that shows leakage of protein in the kidneys, which represents kidney damage. Normal UACR is less than 30 mg/g)
- ✓ with a blood potassium level of no more than 4.8 mmol/L
- ✓ taking the highest recommended or highest manageable dose of a class of drugs which block the renin-angiotensin system (ACE inhibitors or ARBs[†])

Q What happened in the study?

- During this double-blind study, neither the doctors or the participants knew who was taking finerenone and who was taking the placebo
- The study primarily looked at the effect of finerenone on the kidneys and the heart
- The participants had regular check-ups with study doctors for around 3 years



Q What were the analysis results?

Compared with the people who took the placebo, those who took finerenone:

Had a **23% lower risk** of having one or more **kidney problems**, including:

- their kidneys failing
- their eGFR dropping by 57% or more (over 4 or more weeks)
- dying from kidney-related causes



Had a **14% lower risk** of having one or more **heart-related problems**, including:

- a heart attack
- a stroke
- being hospitalized for heart failure
- dying from heart-related causes



Side Effects — The group who took finerenone were more likely to develop **high blood potassium** (which can cause heart problems) than the group who took placebo. In most cases, high blood potassium was manageable, and the person did not have to stop taking finerenone.



KEY TAKEAWAY

Finerenone, in addition to standard-of-care therapies for CKD linked to T2D, reduces the risk of kidney and heart-related problems in people with both T2D and a broad range of CKD severity.

Summary prepared by Charlotte Maddocks of Envision Pharma Group in full collaboration with the original article authors. The graphical abstract represents the opinions of the authors. For a full list of declarations, including funding and author disclosure statements, and copyright information, please see the full text online.

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[†]ACE (angiotensin-converting enzyme) inhibitors and ARBs (angiotensin receptor blockers) are drugs used to lower blood pressure and reduce the amount of protein passing in the urine. Here, they are referred to as "standard-of-care" therapies.