Please note that this summary only contains information from the **full scientific abstract**

Biomarkers in the blood of people with advanced renal cell carcinoma treated with avelumab + axitinib or sunitinib are related to treatment outcomes

JAVELIN

Study number: NCT02684006 **Study start date:** March 2016 **Study end date:** May 2024

The full title of this abstract is: Integrating peripheral biomarker analyses from JAVELIN Renal 101: avelumab + axitinib (A + Ax) vs sunitinib (S) in advanced renal cell carcinoma (aRCC)

Avelumab + axitinib is approved to treat the condition that is discussed in this summary. This summary reports the results of a single study. The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence, not on the results of a single study. This summary reports the results of a planned interim analysis of the study. This means that the study has not yet been completed. The study described is still ongoing, therefore the final outcomes of this study may differ from the outcomes described in this summary.

More information can be found in the scientific abstract of this study, which you can access here:

2021 ASCO Annual Meeting Scientific Abstract

Medical terms pronunciations

Avelumab <a-VEL-yoo-mab>
Axitinib <ax-IT-ih-nib>
Carcinoma <kar-sih-NO-muh>
Sunitinib <soo-NIT-in-ib>

What did this study look at?

- Renal cell carcinoma (RCC) is the most common type of kidney cancer. In RCC, cancer cells form in the tubes of the kidney (known as tubules) that filter and clean the blood.
  - RCC is called advanced RCC (aRCC) when it has spread outside of the kidneys.
- In a study called the JAVELIN Renal 101 trial, researchers wanted to find out if treatment with avelumab + axitinib could slow down aRCC compared to treatment with sunitinib, a standard treatment at the time of study.
- Avelumab is a type of medicine called immunotherapy. It has been approved as a first treatment, in combination with axitinib, for people with aRCC. Avelumab is given as a drip (infusion) into a vein.
  - Immunotherapy is a type of treatment that helps the body's immune system fight cancer.
  - Cancer cells are often covered with a protein called PD-L1, which hides them from the immune system. This stops the immune system from finding and killing the cancer cells.
  - Avelumab works by attaching to this PD-L1 protein to stop it from working. This releases the "brakes" on the immune system, which may help it to start working again and kill cancer cells.
- Axitinib is a type of medicine that people take as a tablet by mouth to treat aRCC.
  - Axitinib stops a protein called VEGF from working. VEGF is made by many cells in the body, including cancer cells.
  - The VEGF protein tells the body to grow blood vessels so it can bring blood to the cells.
  - Cancer cells use VEGF to tell the body to bring blood to tumors, causing them to grow.
  - When you take axitinib, it can help slow down the growth of cancer cells.
- Sunitinib is another type of medicine that people take as a capsule by mouth to treat aRCC.
  - Sunitinib attaches to proteins in the body called RTKs. These RTK proteins help tell the body when it needs to do something, like grow.
  - Cancer cells use RTK proteins to tell tumors to grow and spread.
  - When sunitinib attaches to RTK proteins, it can help stop tumor cells from spreading and growing.
- People taking part in the JAVELIN Renal 101 trial were put into different groups based on the type of treatment they received (avelumab and axitinib together or sunitinib alone). It was decided by chance (like flipping a coin) which group people would be put into.
  - To compare the treatments, researchers looked at how long people lived after receiving the treatments and how well the treatments made tumors shrink or disappear. They also looked at how long people lived without their cancer getting worse.
- In a follow-up investigation, researchers wanted to find out if certain "biomarkers" in the blood might be related to how people with aRCC respond to treatment with either avelumab + axitinib or sunitinib.
  - A biomarker is something that can be used to predict how a person might respond to different treatments.
  - Biomarkers can also be used to understand how cancer and different treatments work.
  - The biomarkers investigated here were immune cells and proteins that are present in the blood.
  - The researchers took blood samples from people with aRCC before and during treatment with either avelumab + axitinib or sunitinib.
  - Researchers looked for differences in biomarkers between the blood samples from both groups and how they were related to treatment results.

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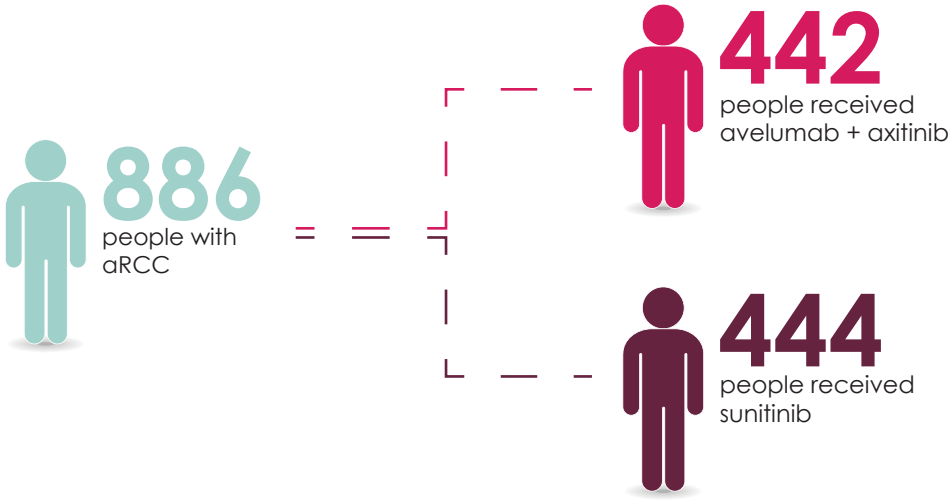
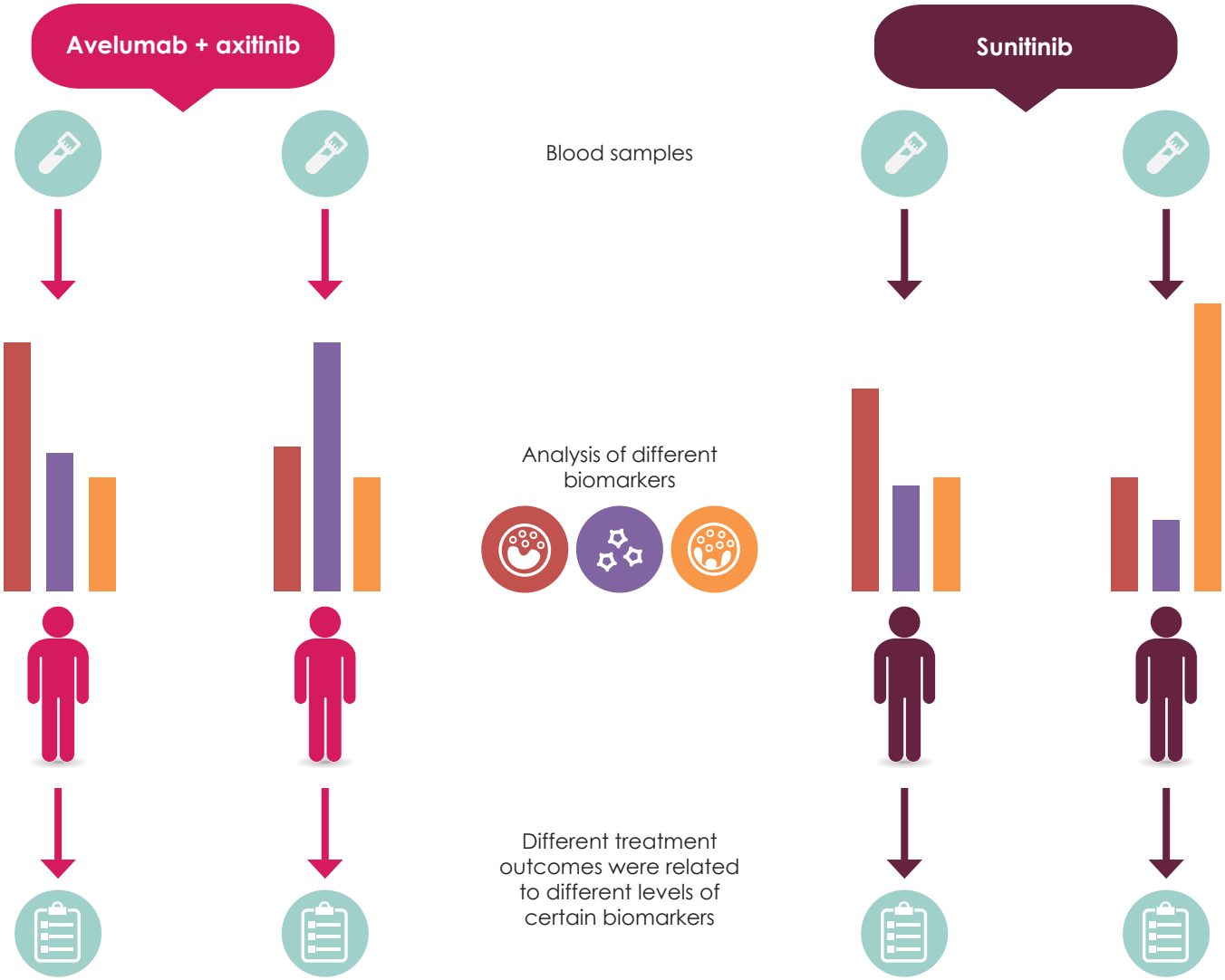
Who took part in this study?



What were the results of the study?

The researchers noticed trends in the levels of certain biomarkers in people receiving avelumab + axitinib compared with people receiving sunitinib, both before and during treatment



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What were the results of the study? (continued)

People in both treatment groups had high or low levels of a certain biomarker, which was related to whether or not they benefited from treatment with avelumab + axitinib or sunitnib.

Levels of several biomarkers that were measured before and during study treatment were related to how long at least half of the people lived without their cancer getting worse.

Cancer cells had genetic variations that were related to the different biomarker levels. These variations might affect how people with aRCC respond to treatment.

More results from this study can be found here: View Scientific Abstract

What was the main conclusion reported by the researchers?

- This study showed that the level of certain biomarkers in the blood of people with aRCC is related to how people responded to treatment with either avelumab + axitinib or sunitinib. This could help health professionals predict how a person will respond to treatment with avelumab + axitinib compared to sunitinib.

Who sponsored this study?

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The sponsors would like to thank all of the people who took part in this study.

Further information

For more information on this study, please visit:
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https://clinicaltrials.gov/ct2/show/NCT02684006

For more information on clinical studies in general, please visit:
https://www.clinicaltrials.gov/ct2/about-studies/learn
https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials.html

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