

Comparison of outcomes in people with metastatic renal cell carcinoma treated with avelumab + axitinib or sunitinib after all or part of their kidney was removed

JAVELIN

The full title of this abstract is: Role of prior nephrectomy for synchronous metastatic renal cell carcinoma (mRCC) on efficacy in patients treated with avelumab + axitinib (A + Ax) or sunitinib (S): results from JAVELIN Renal 101

Please note that this summary contains information from the scientific abstract:

[View scientific abstract](#)



Date of summary: September 2021

For more information on this study, go to:
<https://clinicaltrials.gov/ct2/show/NCT02684006>

What is the key takeaway from this study?

- This study looked at people with renal cell carcinoma whose cancer had already spread outside the kidneys when it was first detected. The study looked at whether these people had better outcomes with either avelumab + axitinib or sunitinib based on whether or not they had their kidney removed before starting treatment
- People who took avelumab + axitinib had better outcomes if they had their kidney removed before starting treatment compared with people who did not
- The researchers saw no difference in outcomes for people who took sunitinib whether or not they had their kidney removed before starting treatment



Medical term pronunciations

Avelumab <a-VEL-yoo-mab>
Axitinib <ax-IT-ih-nib>

Carcinoma <kar-sih-NO-muh>
Nephrectomy <nuh-FREK-tu-me>

Sunitinib <soo-NIT-in-ib>

What did this study look at?

What is metastatic renal cell carcinoma?

- Renal cell carcinoma (RCC) is the most common type of kidney cancer. In RCC, cancer cells form within the tubes of the kidney that filter and clean blood
- RCC is called metastatic RCC (mRCC) when it has spread outside the kidneys. Sometimes, this has already happened when the cancer is first detected
- In some people with RCC, surgeons will remove some or all of the kidney to help control the cancer. This is called nephrectomy



What are avelumab, axitinib, and sunitinib?

- These are medicines that are used to treat people with mRCC



Avelumab is a type of medicine called immunotherapy. Avelumab treatment can help the immune system find and destroy cancer cells. Avelumab is given as a drip (infusion) into the vein



Axitinib can help slow down the growth of cancer cells. It does this by stopping a protein called VEGFR from working. VEGFR is made by many cells in the body, including cancer cells. VEGFR tells the body to grow blood vessels so it can bring blood to the cells. Axitinib is taken as a tablet by mouth



The use of avelumab + axitinib together is approved as a first treatment for people with mRCC



Sunitinib can help stop cancer cells from spreading and growing. It does this by stopping proteins called RTKs from working. Cancer cells use RTK proteins to tell tumours to grow and spread. Sunitinib is taken as a capsule by mouth

What was the purpose of the JAVELIN Renal 101 study?

- In a study called JAVELIN Renal 101, researchers wanted to know if treatment with avelumab + axitinib together could slow the growth of mRCC compared with sunitinib treatment. Sunitinib was a standard treatment at the time of the study

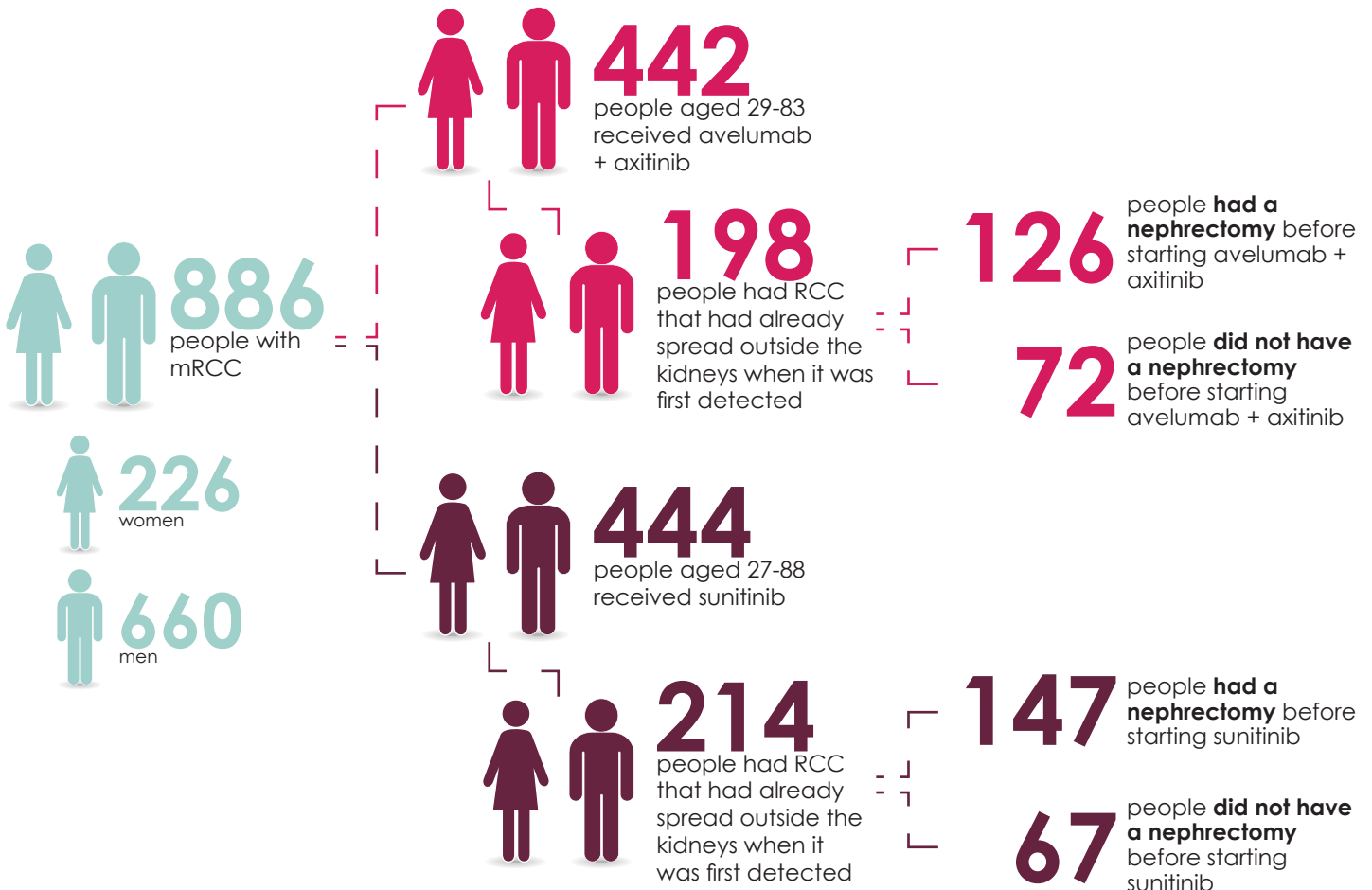
In this follow-up study, researchers wanted to know:

Does treatment with avelumab + axitinib or sunitinib work differently in people with mRCC whose cancer had already spread outside the kidneys when it was first detected and who had a nephrectomy before starting treatment?

What happened during the study?

How was the study done?

- People taking part in the JAVELIN Renal 101 trial were put into different treatment groups (avelumab + axitinib together or sunitinib)
 - It was decided by chance (like flipping a coin) which group people would be put into
 - JAVELIN Renal 101 began in March 2016 and will be completed in May 2024
 - People took part at 278 locations in 21 countries in North America, Europe, and Asia
- In this follow-up study, people whose cancer had already spread outside the kidneys when it was first detected were further divided into subgroups. These subgroups were based on whether or not they had a nephrectomy before taking either avelumab + axitinib or sunitinib. Researchers compared the outcomes of people in each subgroup
 - This was not a preplanned analysis, and the results are not definitive



- Researchers wanted to find out if treatment with avelumab + axitinib or sunitinib worked differently in people who had a nephrectomy. They looked at:



1. How long people lived with their cancer without it getting worse



2. How long patients lived after taking each treatment



3. How well the treatments made tumours shrink or disappear

Continued →

What were the results of the study?

- In people with mRCC whose cancer had already spread outside the kidneys when it was first detected:

Treatment with avelumab + axitinib



People were more likely to live longer with their cancer without it getting worse if they had a nephrectomy before taking avelumab + axitinib than if they had not had a nephrectomy



People who had a nephrectomy before taking avelumab + axitinib had a lower risk of dying (41% lower) than those who had not had a nephrectomy



Avelumab + axitinib was better at shrinking tumours or making them disappear in people who had a nephrectomy before starting treatment than in people who had not had a nephrectomy

Treatment with sunitinib

Researchers found no differences in outcomes for people who took sunitinib based on whether or not they had a nephrectomy before starting treatment

What were the main conclusions reported by the researchers?

- The JAVELIN Renal 101 trial showed that people with mRCC were more likely to live longer with their cancer without it getting worse if they took avelumab + axitinib versus sunitinib
- In this follow-up study from the JAVELIN Renal 101 trial, researchers found that people with mRCC whose cancer had already spread outside the kidneys when it was first detected had better outcomes if they had a nephrectomy before taking avelumab + axitinib
- People who took sunitinib had similar outcomes whether or not they had a nephrectomy before starting treatment

Disclaimers

Avelumab + axitinib and sunitinib are 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.

Who sponsored this study?

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Where can I find more information?

For more information on this study, please visit:
[ESMO Congress 2021 Scientific Abstract](https://www.esmo.org/2021/abstracts/abstract-100004755)
<https://clinicaltrials.gov/ct2/show/NCT02684006>

For more information on clinical studies in general, please visit:
<https://www.clinicaltrials.gov/ct2/about-studies/learn>
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