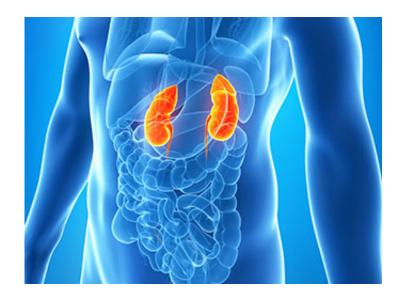


Changing renal cell carcinoma therapy can significantly improve results

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Renal cell carcinoma: therapy change can significantly improve treatment result

A research team of the Comprehensive Cancer Center (CCC) of MedUni Vienna and AKH Vienna was able to demonstrate that a therapy change in the area of metastasising renal cell carcinoma significantly increases the life average expectancy and clearly improves the compatibility of the therapy. The extent of the influence of the administration rhythm of Sunitinib, an effective ingredient which is utilised in the target-oriented therapy, on the treatment results was examined. The result: In 71% of the patients, the therapy change resulted in an average survival extension of 33 months to approximately 75 months.



Sunitinib, a so-called "small molecule", inhibits the growth of the tumour cells by interrupting certain signal paths of the cell and has been applied in the treatment of metastasising renal cell carcinoma for many years. Manuela Schmidinger, University Clinic for Internal Medicine I of MedUni Vienna and the AKH Vienna as well as member of the CCC, about the work: "We are permanently working on the improvement of therapies available to us. This means that we not only research new substances, but also try to combine existing substances efficiently or optimise the dosage or administration scheme. With this therapy we want to test whether our patients benefit from a different administration rhythm."

Cycle truncated

Generally, the effective ingredient is administered once a day in form of a capsule over a period of four weeks. This is followed by a two-week break. The treating physician decides over the number of necessary cycles. In the context of the therapy change, the preparation was only administered for two weeks, followed by a mere one-week break.

The results are clear: the change of the administration rhythm has led to an average extension of life expectancy of 33 months to approx. 75 months in 71% of the patients. This improvement, compared to historical data, can be explained with the fact that a two-week therapy break is too long, allowing the tumour to grow again. Another reason for the improved life expectancy could be that the therapy is more compatible due to this administration rhythm, thus allowing fewer dosage reductions. In this context, Schmidinger and her colleagues detected a reduction of the side effects to the therapy. For example, conventional side effects such as fatigue, inflammations and pain in the oral mucosa, nausea or the hand-foot syndrome could be significantly reduced. The data was presented at ASCO 2015, the world's largest cancer congress. In autumn 2015, an update of the data confirmed the



results.

About renal carcinoma

Every year, approx. 1,230 people in Austria face the diagnosis of renal carcinoma. Most of them suffer from a renal cell carcinoma, the most frequent type of malignant kidney tumours. The chances of a cure depend strongly on the stadium at which the tumour is diagnosed. If the tumour has already formed metastases, the prognosis is poor—the average <u>life expectancy</u> is 33 months.

MedUni Vienna and AKH Vienna offer welcoming news also in the immune therapy sector: in the context of a "Named Patient Program", the substance Nivolumab is already used in the treatment of renal cell carcinoma. Schmidinger: "This is extremely positive, because the European Medicines Agency (EMEA) is expected to approve the mediation for this application sector only in spring. The reason why we are able to apply Nivolumab in a "Named Patient Program" is that a phase III study has demonstrated a clear survival advantage of the patients.

Nivolumab is already approved for the treatment of malignant melanomas and lung cancer. A "Named Patient Program" is a program whereby therapies are applied which are only approved for other indications or in other countries. Patients, who have exhausted all therapy options or do not comply with study criteria, benefit from this program if a significant therapy success can be expected.

Provided by Medical University of Vienna

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