

Immunotherapy effective as first-line treatment for advanced head and neck cancer

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Immunotherapy on its own is better than aggressive chemotherapy as a first-line treatment for advanced head and neck cancer, according to surprising new data from a major phase III clinical trial.

Patients lived for longer and had far lower rates of side-effects if they took the immunotherapy drug <u>pembrolizumab</u> than those who received an 'extreme' combination of two chemotherapies and a targeted drug.

People with an immune hallmark called PD-L1 in their tumours did particularly well on pembrolizumab—living for around 40 per cent longer.

And while only around a fifth of patients overall responded to pembrolizumab, those who did so often did spectacularly well—with a median length of response of 20.9 months compared with only 4.2 months with aggressive chemotherapy.

The trial was led in the UK by a team at The Institute of Cancer Research, London, and The Royal Marsden NHS Foundation Trust, and involved 206 research centres worldwide.

Its findings could in future see immunotherapy become a standard, first-line <u>treatment</u> for advanced head and neck <u>cancer</u>, and spare many patients the side-effects associated with combination chemotherapy.

The study is being presented at the European Society for Medical



Oncology (ESMO) Congress 2018 in Munich today (Monday), and was sponsored by Merck & Co., Inc.

Patients would normally be given aggressive chemotherapy if diagnosed at an advanced stage when the cancer has begun to spread to try to get rid of all the cancer cells as quickly as possible.

But the new trial sought to see if immunotherapy, in combination with chemotherapy or on its own, could be a more effective and kinder option.

The researchers randomly assigned 882 patients in equal numbers to one of three treatment groups—receiving the 'extreme' chemotherapy combination, and the immunotherapy pembrolizumab with platinum chemotherapy or on its own.

Patients with high levels of the immune marker PD-L1 in their tumours received the biggest benefit from pembrolizumab—living for a median of 14.9 months after diagnosis compared with 10.7 months with the aggressive combination.

But patients with lower levels of PD-L1 also saw benefit, living 12.3 months taking pembrolizumab compared with 10.3 for those who received the combination.

Importantly, only 17 per cent of patient experienced serious side-effects with pembrolizumab, compared with 69 per cent of those taking the 'extreme' therapy.

The only downside to pembrolizumab on its own was that fewer people in total responded. Even in the group with high levels of PD-L1, 23 per cent of patients who received the treatment responded, compared with 36 per cent for chemotherapy.



The response rate was higher, at 36 per cent, for patients who received platinum chemotherapy alongside pembrolizumab—but these patients had the same high rate of side-effects as those on the aggressive chemotherapy combination.

Pembrolizumab is an immune checkpoint inhibitor that targets PD-L1 on the surface of cancer cells. Blocking PD-L1 in this way takes the 'brakes' off the immune system, setting it free to attack cancer cells.

The findings are consistent with previous studies of checkpoint inhibitor immunotherapies and illustrate the pros and cons of these drugs—their excellent responses in some patients, but the fact that only a minority of patients respond.

Professor Kevin Harrington, Professor of Biological Cancer Therapies at The Institute of Cancer research, London and Consultant Clinical Oncologist at The Royal Marsden Foundation Trust, said:

"Our study has shown that the immunotherapy pembrolizumab on its own is better than an aggressive triple-whammy of two types of chemotherapy plus a targeted drug as first-line treatment for advanced head and neck cancer.

"We couldn't believe it when we saw the results. None of us expected pembrolizumab on its own to work so well in some of these patients—and it raises the prospect that we could spare some people chemotherapy altogether.

"The study could have major implications for the treatment of advanced head and neck cancers—taking immunotherapy from a last resort to the treatment we turn to first for some patients. The trial is still ongoing, but we expect some patients to go on to live for years longer than they would have done had they received standard chemotherapy."



Professor Paul Workman, Chief Executive of The Institute of Cancer Research, London, said:

"We're used to seeing immunotherapy trialled in patients who have exhausted other options—but this trial has shown its true potential as a smarter, kinder and more effective first-line treatment for cancer, where it can have the biggest impact on a patient's life.

"This trial showed the benefits of immunotherapy in head and <u>neck</u> <u>cancer</u>, but I'm optimistic that the same will hold true for other cancers. We now need to do two things to ensure more patients can benefit from <u>immunotherapy</u>—develop ways of getting these drugs to work in a higher proportion of <u>patients</u>, and come to an agreement over the cost of these drugs to make them more affordable for the NHS."

Provided by Institute of Cancer Research

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