

Immunotherapy better than aggressive chemo as first-line treatment in head and neck cancer

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Immunotherapy used with chemotherapy or on its own is a better first-line treatment for people with head and neck cancer that has returned than standard aggressive chemotherapy, new clinical trial results show.

At diagnosis, people with head and <u>neck cancer</u> that has come back or spread are currently given an 'extreme' cocktail of two <u>chemotherapy</u> <u>drugs</u> and a targeted <u>antibody treatment</u>.

But the new trial found that the immunotherapy pembrolizumab in combination with platinum chemotherapy extended survival, while immunotherapy alone also worked well for some <u>patients</u> with much lower rates of side effects.

The new clinical trial results offer strong evidence in favour of pembrolizumab, either on its own or in combination with chemotherapy, becoming the first treatment of choice for people with head and neck cancer that has come back and spread.

NICE has started an analysis of whether pembrolizumab is cost-effective for use on the NHS, and is expected to announce its decision in February 2020.

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.

Scientists found patients lived longer when they were given pembrolizumab in combination with a platinum chemotherapy in the first instance, instead of the current standard treatment of aggressive chemotherapy.

Patients with high levels of the immune marker PD-L1 who received pembrolizumab with chemotherapy lived for an average of 14.7 months, compared with 11.0 months in patients given the aggressive chemotherapy treatment.

Remarkably, a third of patients treated with pembrolizumab and chemotherapy were alive three years after starting treatment, compared with only one in twelve of those receiving extreme chemotherapy.

People with lower levels of PD-L1 also saw benefit from the combination of immunotherapy and chemotherapy, with survival extending to an average of 13.6 months compared with 10.4 months with standard 'extreme' chemotherapy.

The final results of the trial were presented at the ASCO Annual Meeting in Chicago on Saturday. The trial was sponsored by Merck & Co., Inc., known as MSD outside the US and Canada.

Pembrolizumab on its own extended survival in people with the PD-L1 immune marker—who make up the majority of patients—compared with the standard, aggressive chemotherapy combination.

Fewer people responded when given the immunotherapy alone—16.9 per cent compared with 36 per cent with chemotherapy—but this did not prevent pembrolizumab from delivering markedly improved survival rates compared to extreme chemotherapy. For those people for whom



pembrolizumab did work, it worked extremely well—with the average duration of response being 22.6 months compared with just 4.5 months on aggressive chemotherapy.

Importantly, compared with chemotherapy, pembrolizumab treatment came with much lower rates of serious side effects, which occurred in just 55 per cent of people treated with the immunotherapy alone.

Side effects occurred in 85 per cent of people given pembrolizumab with platinum chemotherapy, and in 83 per cent of people who received the aggressive chemotherapy combination.

The research follows a recent announcement by the ICR of a £15 million fundraising drive to complete a new £75 million Centre for Cancer Drug Discovery. The new centre will focus on new anti-evolution drugs and combinations, including use of targeted drugs alongside immunotherapies.

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:

"We have shown that pembrolizumab either on its own or in combination with platinum chemotherapy is effective as a first-line treatment for patients with advanced head and neck cancer—where currently the first choice of treatment is an aggressive chemotherapy.

"We had started to see strong indications of the promise of pembrolizumab as a first-line treatment while the trial was still ongoing, and I am delighted to see the preliminary results of the trial confirmed in the final analysis.

"Patients with advanced head and neck cancer are currently given a



highly aggressive chemotherapy combination, so I'm hopeful that the results of our trial will soon be translated into pembrolizumab approval on the NHS so patients can start benefiting right at the start of treatment. We can imagine that many patients might be treated with pembrolizumab alone, allowing patients the twin benefits of prolonged survival and fewer side effects. Where necessary some might need to receive a combination of pembrolizumab and chemotherapy and we now know that this can be highly beneficial."

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

"Immunotherapy has already revolutionised the outlook for patients with melanoma, and is showing huge promise in other cancer types as well. Based on the results of the new clinical trial, pembrolizumab looks set to do the same for people diagnosed with recurrent head and neck cancer.

"Until now, immunotherapy had only been tested in patients with head and neck <u>cancer</u> at a later stage of treatment, when other therapies had stopped working. I'm keen to see innovative new treatments assessed earlier in the course of treatment where the potential for benefit can be greater, and it's excellent news that in this case <u>pembrolizumab</u> is indeed proving effective at the first-line stage."

Provided by Institute of Cancer Research

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