CheckMate 816 study: nivolumab plus chemotherapy given before surgery for non-small cell lung cancer

Why is this study important?

- Some people with non-small cell lung cancer (NSCLC) have tumors that can be removed surgically. However, the cancer often comes back, ultimately leading to death.
- Taking chemotherapy (chemo) before or after surgery can reduce the risk of cancer returning and help people live longer after surgery. However, this only works in some people.
- Nivolumab (NIVO) is an immunotherapy; it works by helping a person’s immune system attack cancer cells.
- The goal of the CheckMate 816 study was to find out if NIVO plus chemo works better than chemo alone when taken before surgery for NSCLC.

Who took part in this study?

- 358 people from 14 different countries.
- All had tumors in the lungs (and in some cases the nearby lymph nodes) that could be removed with surgery (4 centimeters or larger).
- 7 in 10 were men.
- 6 in 10 had stage IIIA NSCLC.
- Average age: 64 years.
- This study included people with stages IB, IIA, IIB, and IIIA NSCLC.

As the number and letter increases, this represents more cancer and more spread.

What treatments were used?

- The researchers created 2 groups:
  - 179 people NIVO plus chemo group
  - 179 people chemo alone group
- Each treatment was taken once every 3 weeks for a total of 3 times.
- Surgery happened within 6 weeks of the third dose.
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What did the researchers look at?

Event-free survival (EFS)
How long did each person live without the cancer coming back?

Pathological complete response (pCR)
After surgery, were there any cancer cells remaining in the tissue samples from the lungs and lymph nodes?

Overall survival
How long did each person live after starting treatment?

What were the main results?

Most people went on to have surgery in both the NIVO plus chemo and chemo groups

People who took NIVO plus chemo lived longer without the cancer coming back (EFS)

People who were alive at 2 years without the cancer coming back

Median event-free survival

Overall, more people who took NIVO plus chemo were alive 2 years after starting treatment compared with those who took chemo alone

Pathological complete response (pCR)

Overall survival

What side effects did people have?
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What were the side effects?

Most side effects from treatment were mild or moderate.

About 1 in 10 people in each group had a serious side effect from treatment.

A serious side effect is one that is life-threatening, requires going to the hospital, or results in death.

Some people had typical side effects from surgery, mostly mild or moderate.

Few people had severe or life-threatening side effects from surgery.

What do these findings mean?

In CheckMate 816, people who took NIVO plus chemo instead of chemo alone before their surgery:

- Lived longer without the cancer coming back
- Lived longer overall
- Were more likely to have lungs and lymph nodes clear of cancer cells
- Did not have more side effects

NIVO plus chemo is now approved in the United States as a treatment for adults with NSCLC whose tumors are 4 centimeters or larger or have cancer cells inside nearby lymph nodes.