

E3805 Clinical Trial Results Summary

Androgen Deprivation Therapy With or Without Chemotherapy in Treating Patients With Metastatic Prostate Cancer (CHAARTED)

What did this trial involve and who was it for?

This trial was for people with prostate cancer that had spread beyond the prostate. The usual first treatment for this type of prostate cancer includes:

- Hormonal therapy using hormone-lowering medication or surgery to remove the testicles
 - The goal of this treatment is to reduce levels of male hormones, called androgens, to stop them from fueling prostate cancer cell growth. This is also called androgen deprivation therapy (ADT) or testosterone suppression.
- Chemotherapy, usually only given after the cancer has started to grow again
 - Previous research has shown that docetaxel, a chemotherapy drug, can be effective in treating prostate cancer. However, more work was needed when the study was started to confirm the most effective timing to use it.

The purpose of E3805/CHAARTED was to see if giving docetaxel with hormonal therapy, before the prostate cancer worsened, would extend the time that patients lived and their cancer remained stable. A total of 790 study participants were randomly assigned by a computer to receive either:

- The usual care at the time of the study (hormonal therapy only), or
- The usual care plus up to 6 cycles of docetaxel

Patients in both groups continued hormonal therapy until their cancer worsened or side effects became too severe. Patients in the usual care group could then receive docetaxel if their cancer worsened.

What are the results?

- A long-term survival analysis found that patients who received docetaxel in addition to the usual hormonal therapy were more likely to live longer:
 - Half of the patients who received docetaxel with hormonal therapy were alive at 60.4 months, compared to half of the patients who received hormonal therapy alone being alive at 47.2 months.
 - 25.9% of patients who received docetaxel in addition to hormonal therapy were still alive at 10 years, compared to 22.5% of patients who received hormonal therapy alone.
- This survival benefit from receiving both docetaxel and hormonal therapy was greatest for patients who had more widespread disease:
 - For these individuals, half of the patients were alive at 52.7 months, with 20.9% alive at 10 years. In comparison, half of patients with more widespread disease who received hormonal therapy only were still living at 34.4 months, with 11.4% alive at 10 years.
- For individuals with less widespread disease, no survival benefit from the combination was observed.

What do the results mean for patients?

- Adding docetaxel to the usual hormonal therapy before the prostate cancer worsened helped patients with more widespread disease to live longer.
- E3805/CHAARTED was followed by the EA8153/CHAARTED2 trial, which looked at the next step of adding a different chemotherapy drug to hormonal therapy for patients whose prostate cancer worsened.
- Since the CHAARTED trial was conducted, a new treatment with more intense hormonal therapy was also proven to improve survival over testosterone suppression alone. The more intense hormonal therapy plus docetaxel was proven to be more effective than testosterone suppression alone plus docetaxel. Patients and their doctor now choose whether to add docetaxel to the intense hormonal therapy for patients with widespread disease.

For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine: <https://clinicaltrials.gov/study/NCT00309985>
- *Annals of Oncology*: <https://doi.org/10.1016/j.annonc.2025.08.004>
- *New England Journal of Medicine*: <https://www.nejm.org/doi/10.1056/NEJMoa1503747>
- *Journal of Clinical Oncology*: <https://doi.org/10.1200/jco.2017.75.3657>

About ECOG-ACRIN

This trial was led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN). ECOG-ACRIN is a membership-based scientific organization that designs and conducts cancer research involving adults who have or are at risk of developing cancer. ECOG-ACRIN is a component of the National Cancer Institute's National Clinical Trials Network. Learn more at www.ecog-acrin.org.

To all the patients that participated in this trial, thank you. Your participation, and that of other patients like you, made this research possible.