Part 2 of TALAPRO-2, a study on the effects of adding talazoparib to enzalutamide in men with metastatic castration-resistant prostate cancer

What will the researchers report?

The researchers will report the results at a later date. As men are currently joining this study, the researchers will report the results at a later date.

Who will take part in this study?

Around 872 men from different countries will take part.

What did this study look at?

This study will look at how long the men live without their cancer getting worse. This study will also look at how long the men live after starting treatment. The researchers will look at these results for:

- their previous treatment
- their response to treatment
- their overall survival
- whether treatment is effective in reducing the size or number of tumors
- the type of treatment received by men who died
- reasons why men did not complete the study
- reasons for stopping treatment with study drug
- treatment side effects
- any additional treatments that the men received
- any health-related quality of life changes

The men in each group will receive 1 of 2 treatments:

- TALA + ENZA
- Placebo + ENZA

Within each group, men will be given:

- TALA
- ENZA
- Placebo

Further information

For more information on this study, please visit: https://clinicaltrials.gov/ct2/show/NCT03395197

For more information on clinical studies in general, please visit: https://clinicaltrials.gov/ct2/about-studies/learn

Who sponsored this study?

TALAPRO-2 was a Pfizer-funded study. Pfizer Inc., New York, NY 10017

Who will report the results?

Envision Pharma Group, Inc. and was funded by Pfizer.

Funding source

Pfizer Inc.

Date of submission: May 2019

Study start date: November 2017

Estimated study end date: December 2017

Study end date: November 2024

The full title of this abstract is: Part 2 of TALAPRO-2, a phase 3 trial of the anti-angiogenic oral drug talazoparib in combination with enzalutamide in men with metastatic castration-resistant prostate cancer (mCRPC).

Please note that this summary only contains information from the full scientific abstract:

https://meetinglibrary.asco.org/record/177946/abstract

More results from this study can be found here:

http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are

http://www.clinicaltrials.gov/ct2/about-studies/learn

https://meetinglibrary.asco.org/record/177946/abstract

Prostate cancer is one of the most common cancers in men. It often develops because male sex hormones (called androgens) often cause prostate cancer cells to grow. In advanced stages of prostate cancer, the cancer is called castration-resistant prostate cancer (CRPC for short). Prostate cancer can be treated with surgery, radiation, or drugs that lower androgen levels through surgery or hormone therapy (known as castration).

Treatment for prostate cancer usually involves treatment to stop the cancer from spreading. Some men have prostate cancer that does not spread. These men can be watched closely. But some men have prostate cancer that has spread inside the body, it is known as metastatic CRPC (mCRPC for short). In men with mCRPC, the cancer has spread to other parts of the body. If the cancer has spread to other parts of the body, it is known as metastatic CRPC (mCRPC).

Men with mCRPC usually receive treatments that work by lowering androgen levels. One such treatment is enzalutamide (ENZA for short). Enzalutamide is approved to treat the condition under study that is discussed in this summary. Enzalutamide in combination with enzalutamide is not approved to treat the condition under study that is discussed in this summary. Talazoparib in combination with erlotinib is approved in the US to treat people with advanced breast cancer.

Talazoparib (TALA) is a PARP inhibitor that causes cancer cells to die. In cells that are damaged by DNA damage, PARP repair the DNA and allow the cancer cells to survive. In cells that are damaged by DNA damage and have faulty BRCA genes, PARP is not able to repair damaged DNA. So TALA will only work in cells that have faulty BRCA genes. TALA could help TALA to better prevent DNA repair and kill cancer cells in people without faulty BRCA genes.

TALA stops a type of protein called PARP from breaking down PARP inhibitor is a type of chemotherapy drug, if in any men who were taking a chemotherapy drug.

BRCA genes.

• BRCA genes.

• Cancer cells cannot repair their DNA, they will die.

Repaired DNA.

• DNA repair mechanisms.

• This is often due to a faulty BRCA gene, but can also be due to faults in other DNA repair pathways.

• Repairing DNA is also required to repair and kill cancer cells in people without faulty BRCA genes.

• Cells usually have many ways to repair DNA, so TALA will only work in cells that have faulty BRCA genes.

• Even when treatment is effective, some prostate cancer cells will remain.

• If cancer cells cannot repair their DNA, they will die.

• This is often due to a faulty BRCA gene, but can also be due to faults in other DNA repair pathways.

• If cancer cells cannot repair their DNA, they will die.

• Cells usually have many ways to repair DNA, so TALA will only work in cells that have faulty BRCA genes.

• Enzalutamide (ENZA for short) is a drug approved to treat men with mCRPC. It is currently being investigated in this study to improve outcomes in men with mCRPC.

• TALA stops a type of protein called PARP from breaking down PARP.

• Repairing DNA is also required to repair and kill cancer cells in people without faulty BRCA genes.

• Cells usually have many ways to repair DNA, so TALA will only work in cells that have faulty BRCA genes.