

Repurposing the Prostate Cancer Drug Degarelix to Treat Bladder Cancer



BROWN
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PROPOSED TREATMENT

Incorporating degarelix into the current standard therapy for BC patients who are testosterone receptor positive.

Men are 3-4 times more likely to develop BC than women. One potential cause for the observed difference in BC rates could be that testosterone drives or supports progression of BC. A previous study has shown that, when exposed to a chemical known to cause BC, male rodents that are treated with testosterone ablating therapies are less likely to develop BC than male rodents with normal testosterone activity.

In addition, it has been shown that men who take testosterone reducing agents for prostate issues are less likely to develop BC than men with normal testosterone activity. Furthermore, men taking testosterone lowering agents for prostate cancer, who are also treated for BC, have a 50% lower BC recurrence rate than men with normal testosterone levels.

Degarelix is a medication that lowers testosterone levels and is FDA approved to treat prostate cancer. We propose the addition of degarelix to standard chemotherapy before surgery to improve complete response rates (a surrogate of cure rates) in testosterone receptor-positive BC.

SUMMARY STATEMENT

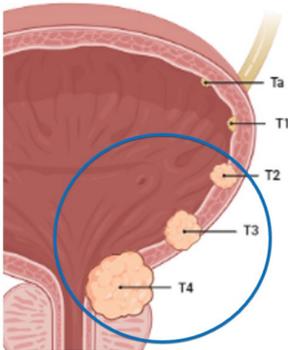
Assessing the efficacy of adding degarelix to the current standard therapy for androgen receptor-positive bladder cancer in order to improve patient outcomes

DISEASE/CONDITION

Over 80,000 people are expected to be diagnosed with bladder cancer (BC) in the USA in 2022, with more than 17,000 deaths. Worldwide, over 573,000 new cases with over 212,500 deaths are expected.

There are several risk factors that increase a person's chances of developing BC, including age, tobacco use, family history, exposure to environmental factors, and being a male (while BC is the 4th most common cancer in men, it is not even one of the top 10 in women). Research studies support the hypothesis that testosterone drives or supports progression of BC.

CURRENT TREATMENT



Patients with non-muscle invasive BC are often treated with surgical removal of the tumor alone. However, patients with muscle-invasive BC have higher risk disease and thus are treated more aggressively, with chemotherapy followed by surgical removal of the entire bladder. About 35% of these patients have a complete response to treatment, and they have a median survival of 13.6 years.

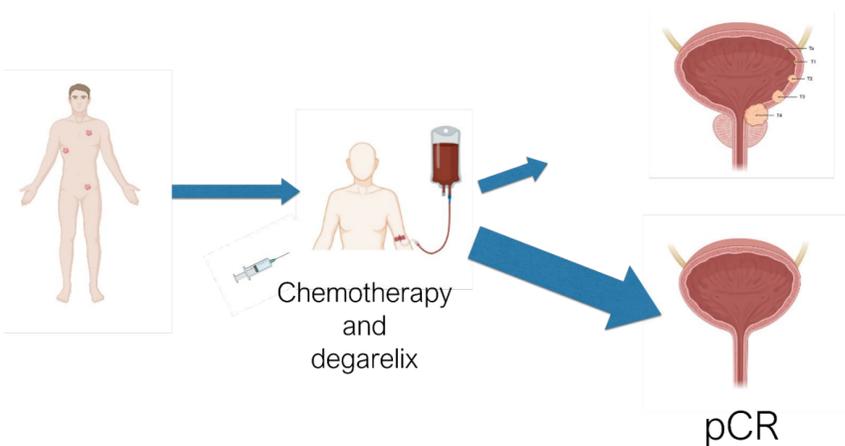
Patients who have muscle-invasive BC after chemotherapy have a median survival of only 3.7 years. New ways to achieve a complete response to treatment are critical to improving patient survival.

PROJECT

A non-randomized, unblinded pilot study to analyze the efficacy of adding degarelix to chemotherapy prior to surgery for BC patients.

This study will enroll 20 testosterone receptor-positive BC patients in the first stage. If there is a signal for efficacy, we will enroll an additional 12 patients in the second stage, for a total of 32 patients. Since testosterone receptors are found in BC tissue in both men and women, both sexes are eligible for enrollment.

The primary outcome will be the complete response rate and will be compared to the historical rate of 35%. We hypothesize that the addition of degarelix to chemotherapy will increase complete response rates from 35% to 50%.



If this pilot study is successful, we will plan a larger, randomized controlled phase IIB (or phase III) study. Improved therapeutic outcomes in our study could lead to practice-changing therapy not only for muscle-invasive BC, but also for non-muscle invasive BC and metastatic BC for both men and women.



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