CLINICAL STUDY RESULTS

A Study to Learn About the Effect and Safety of Triptorelin 6-month Formulation in Chinese People with Advanced Prostate Cancer

Overall, the results suggest that triptorelin 6-month formulation was able to achieve and keep the testosterone levels low in Chinese participants with advanced prostate cancer.
The results shown in this summary represent one clinical study. Other clinical studies may produce different results.

This lay summary was created by Ipsen with the assistance of a third-party writing service provider

What was the study about?

The purpose of this study was to learn about the effects and safety of triptorelin 6-month formulation in Chinese people with advanced prostate cancer.

Formulation of drug means the form in which it is made, like a tablet, a syrup or an injection.

Prostate cancer is a cancer that affects the gland producing semen in male. Advanced prostate cancer occurs when cancer has grown or spread beyond the prostate gland. It can be locally advanced, meaning the cancer has reached nearby tissues, or metastatic, meaning it has spread to distant body parts. People with advanced prostate cancer usually have symptoms such as bone pain, difficulty urinating, and extreme tiredness.

Currently, the treatment available for prostate cancer are medicines and surgery that lowers the male sex hormone (testosterone). Hormones are chemical messengers in the body. They help body organs to work in specific ways. Testosterone can help prostate cancer cells grow in some cases.

Triptorelin is a drug that helps to keep testosterone levels low in the body. By reducing testosterone, triptorelin can slow down or stop the growth of these cancer cells.

Triptorelin 6-month formulation is already approved for treating prostate cancer in China. This 6-month formulation releases the drug slowly and helps keep the testosterone levels low. It is given as an injection every six months.

The aim of this study was:

> To find out if a single injection of triptorelin 6-month formulation can lower testosterone levels within 1 month and keep them low for up to 6 months.

The study took place between November 2022 and August 2024 at 31 study sites in China.

Who took part in this study?

195

MEN

71 YEARS

AVERAGE AGE

To take part in the study, participants had to be:

- male and over 18 years old,
- diagnosed with locally advanced or metastatic prostate cancer that is getting worse after the last treatment,

- have blood testosterone levels at a certain level (more than 150 ng/dL*) before participating in the study,
  *ng/dL, or nanograms per decilitre, is a unit to measure very small quantities.
- expected to live for 12 or more months, and
- able to carry out daily activities or able to walk and do light work.

Participants could not take part in the study if:

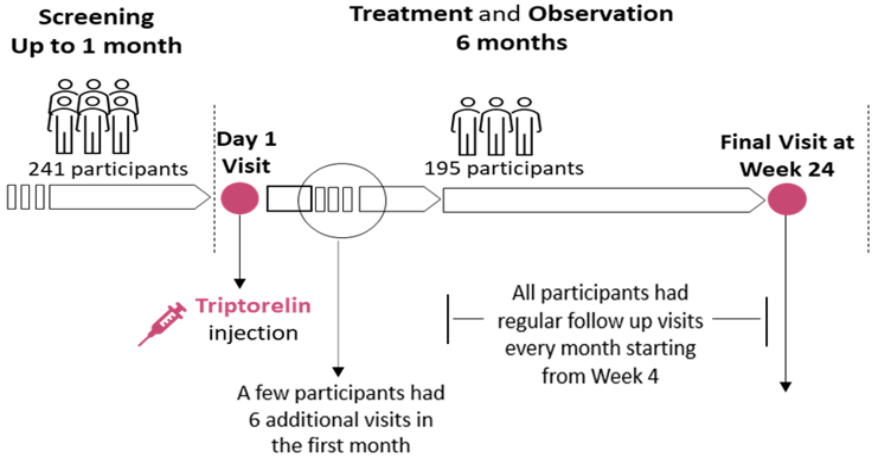
- they had a health condition(s) or had received treatment(s) that could affect the result of the study.

What treatments were used in this study?

Study Treatment

Triptorelin 6-month formulation was given as an injection into the muscle (the buttock) at a dose of 22.5 mg on the first day of the study.

This study had 2 parts:
Screening: The study doctor checked if participants could take part in this study within 1 month before starting the study treatment.
Treatment: Participants received a single injection of triptorelin on Day 1.
All participants had regular visits to check their health and see how well the treatment worked.



The additional visits were to check what happens to the blood levels of triptorelin in the body, during the study duration, in a smaller number of participants before checking them in all the participants.

This study was open-label. This means that the researchers and the participants knew that all participants received triptorelin 6-month formulation.
Final check-ups and tests were done in Week 24 (6 months). If a participant left the study early, the final check-ups were done on their last visit.
The full study lasted about 1 year and 9 months.

What did researchers find out in the study?

Triptorelin 6-month formulation was able to achieve and keep the testosterone levels low in Chinese participants with advanced prostate cancer

Researchers measured the amount of testosterone in the participants' blood at several timepoints throughout the treatment period. They counted the number of participants with castrate levels of testosterone, which is below 50 ng/dL. Castration means using surgery or drugs to prevent the effects of male hormones.

188 out of the 195 participants who were treated were checked for the results. The remaining 7 participants left the study by their own decision or by doctor's decision.

How many participants reached low levels of testosterone in 1 month after a single injection of triptorelin 6-month formulation?

Nearly all the participants, 99.5% (187 out of 188), reached testosterone levels below 50 ng/dL in 1 month after a single injection of triptorelin 6-month formulation.

How many participants could maintain low testosterone levels in blood until 6 months after a single injection of triptorelin 6-month formulation?

All the participants, 100% (188 out of 188), maintained low testosterone levels until 6-months after a single injection.

How did the treatment make participants feel?

During the study, participants were asked to report any 'adverse events', that is, if they felt unwell, experienced any kind of medical event, or noticed anything different about their bodies. Researchers recorded all adverse events reported by participants, whatever the cause. For example, some participants caught COVID-19, and this was reported as an adverse event, although it was not related to the study treatment.

If the study doctor thinks an adverse event may be related to the study treatment, it is called a 'side effect'. A side effect is considered 'serious' when it is life-threatening (event in which the patient was at risk of death at the time of the event), causes lasting problems, or leads to hospitalisation.

- Adverse events that are life-threatening, cause lasting problems or require an individual to go to the hospital are considered serious.
- Less than 1% (1 out of 195 participants) in this study experienced serious side effects.
- No participants died during the study.

Overall, 42% (81 out of 195 participants) experienced a side effect:

No participant stopped taking part in the study because of side effects.

The most commonly reported side effects, reported by 5 or more participants, are shown below. This is shown both as a percentage (%) followed by the actual number of participants in the group (e.g. 8% or 15 out of 195).

Side Effects	Study Treatment (195 Participants)
Excessive sweating	8% (15 out of 195) 
Hot flush	6% (11 out of 195) 
An increase in a liver enzyme called alanine aminotransferase in the blood*	5% (9 out of 195) 
An increase in a liver enzyme aspartate aminotransferase in the blood*	4% (7 out of 195) 
Low haemoglobin levels in blood	3% (5 out of 195) 

*The levels of different liver enzymes in blood tells about the health of liver.
†Haemoglobin is the protein in red blood cells that carries oxygen around the body.

More information

To learn more about this study, please visit:

- ClinicalTrials.gov and search for study NCT05590793

For more information about current treatments available, please speak to your healthcare provider. If you have any questions about this study, please contact the sponsor, Ipsen at:

clinical.trials@ipsen.com

Future research

There is no future research planned with triptorelin 6-month formulation.

Study identification and other information

FULL STUDY TITLE: A multicentre, open-label, single-arm study to investigate the efficacy and safety of triptorelin pamoate 22.5 mg 6-month formulation in Chinese patients with locally advanced or metastatic prostate cancer

STUDY NUMBERS: United States: NCT05590793

PROTOCOL: D-CN-52014-237

OTHER INFORMATION: This was a Phase 3 study. In general, a Phase 3 study tests the study drug on a large number of participants to confirm it works well and how safe it is.

We thank all the participants who took part in this study. Without their support, advances in treatments for medical conditions would not be possible.

We would also like to thank the people who took the time to review this document to make it easier for the general audience to read.