# CLINICAL STUDY RESULTS

## A study to learn about the effects and safety of triptorelin 6-month formulation injected under the skin in men living with prostate cancer

Overall, the results suggest that triptorelin 6-month formulation injected under the skin keeps testosterone levels low in participants with 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



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## What was the study about?

The purpose of this study was to learn about the effects and safety of triptorelin 6-month formulation injected under the skin in people with locally advanced and/or metastatic prostate cancer.

Prostate cancer is the second most common cancer in men, mainly affecting those over the age of 50. Locally advanced and/or metastatic means that the cancer has spread beyond the prostate gland.

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

Triptorelin can be given as an injection every 3 months (3-month formulation) or every 6 months (6-month formulation).

Triptorelin 6-month formulation is already approved and marketed to be given as an injection into the muscle (intramuscular administration). The aim of this study was to develop a new formulation of triptorelin 6-month formulation for subcutaneous administration. This means that the medicine is to be given as an injection under the skin, which is easier to give than an injection into the muscle.

*The main question that the researchers wanted to answer was: Does triptorelin 6-month formulation injected under the skin keep testosterone levels low in participants with locally advanced and/or metastatic prostate cancer?*

The study took place between August 2022 and July 2024 at 26 study sites in the Czech Republic, France, Germany, Lithuania, Netherlands, and Spain.

## Who took part in this study?

145

MEN

72 YEARS

AVERAGE AGE

To take part in the study, participants had to:

- be aged 18 years or older,
- be diagnosed with prostate cancer that required treatment to lower testosterone levels in the body for at least 18 months, and had already been receiving such treatment for at least 3 months with a class of drugs called GnRH analogue* before taking part in the study,
  *GnRH analogues are synthetic drugs that mimic the action of the natural hormone gonadotropin-releasing hormone (GnRH). Triptorelin belongs to this class of drugs.
- have blood testosterone levels below a certain level (50 ng/dL*) before participating in the study,
  *ng/dL, or nanograms per deciliter, is a unit to measure very small quantities
- be either fully active or able to walk and do light work.

Participants could not take part in the study if:

- they had a health condition or had received treatment that could affect testosterone level evaluation.

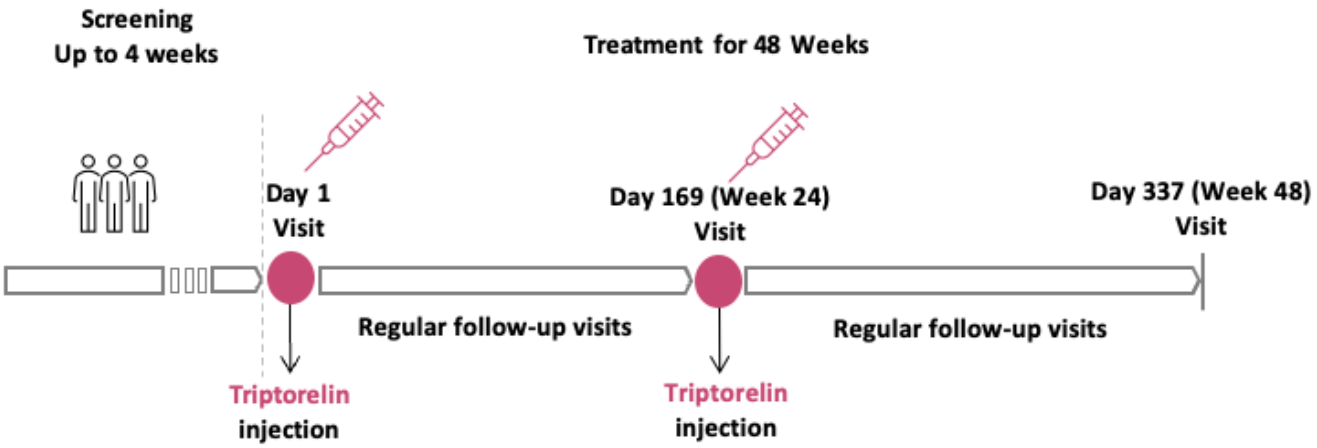
## What treatments were used in this study?

**Study Treatment**

Triptorelin 6-month formulation was given as an injection under the skin at a dose of 22.5 milligrams (mg) on Day 1 and Day 169 (Week 24)

This study had 2 periods:
**Screening:** The study doctor checked if participants could take part in this study within 4 weeks before starting the study treatment.

**Treatment:**
The figure below shows what happened during the treatment period.




This study was an “open label” one. This means that the researchers and the participants knew that participants received triptorelin 6-month formulation.

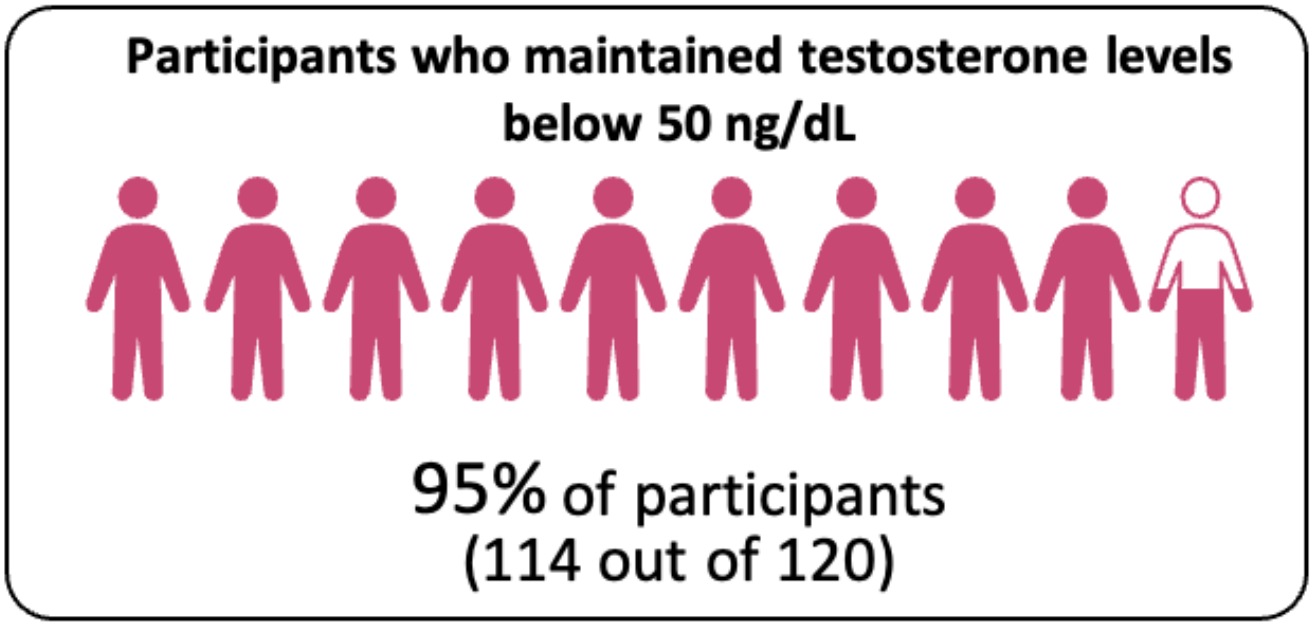
## What were the results of the study?

**Triptorelin 6-month formulation injected under the skin keeps testosterone levels low in participants with locally advanced and/or metastatic prostate cancer**

### How many participants kept testosterone levels in the blood below a certain threshold (50 ng/dL) throughout the treatment?

Researchers measured the amount of testosterone in the participants' blood at several timepoints throughout the treatment period. They counted the number of participants whose level of testosterone in the blood remained below 50 ng/dL, which is considered the desired target. Only participants whose responses could be properly assessed were included in the results.

95% (114 out of 120) of participants maintained testosterone levels below 50 ng/dL.



## 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 causes death, is life-threatening (event in which the patient was at risk of death at the time of the event), causes lasting health problems, is a health condition present at birth, is a medically important event, or leads to new or longer hospitalisation.

- Less than 1% (1 out of 145) of participants in this study experienced a serious side effect.
- 4 participants died during the study, none due to a side effect.

Overall, 32% (46 out of 145) of participants experienced a side effect.

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

The most common side effects reported by 3 or more participants are shown below.

| Side Effects | Triptorelin 6-month formulation (145 Participants) |
|---|---|
| **Hot flush** | 9% (13 out of 145)  |
| **Extreme tiredness** | 5% (7 out of 145)  |
| **Hard, raised area at the site of injection** | 5% (7 out of 145)  |
| **Bruise at the site of injection** | 3% (5 out of 145)  |
| **High blood pressure** | 3% (5 out of 145)  |
| **Muscle pain** | 2% (3 out of 145)  |

## More information

To learn more about this study, please visit:

- ClinicalTrials.gov and search for study NCT05458856
- Clinicaltrialsregister.eu/ctr-search/search and search for study 2021-005719-29

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: An open-label, multicentre, single arm study to assess the efficacy and safety of triptorelin 6-month formulation administered subcutaneously in participants with locally advanced and/or metastatic prostate cancer previously treated and castrated with a GnRH analogue

STUDY NUMBERS: Europe: 2021-005719-29 | United States: NCT05458856

PROTOCOL: D-FR-52014-245

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 in this study. Without their support, advances in treatments for medical conditions would not be possible.