kofam

Koordinationsstelle Forschung am Menschen

BEISPIELSTUDIE

Enzalutamide monotherapy in hormone-naive prostate cancer: primary analysis of an open-label, single-arm, phase 2 study

KATEGORISIERUNG

Gattung
Forschungsprojekt mit lebenden Personen

Art

Unterart
Klinischer Versuch mit Arzneimitteln (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g MepV)

BACKGROUND

The androgen receptor inhibitor enzalutamide (Xtandi®) was approved to treat metastatic castration-resistant prostate cancer that has progressed on docetaxel. This study assessed the activity and safety of enzalutamide monotherapy in men with hormone-naive prostate cancer.

METHODS

Men at least 18 years old, with hormone-naive prostate cancer, for whom hormone therapy was indicated, and who had non-castration levels of testosterone and prostate-specific antigen of 2 ng/mL or greater at screening, and an Eastern Cooperative Oncology Group score of 0, received oral enzalutamide (Xtandi®) 160 mg/day. The primary outcome, measured at week 25, was the proportion of patients in whom a prostate-specific antigen had declined 80% or more.

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?
Ja

BECAUSE
This project was based on a study protocol that defines the exact procedures to be used. It includes a relatively large number of persons and is not based on individual cases ("method-driven search for generalizable knowledge"); thus, it is classified as research according to HRA). Men 18 years or older ("persons"), with hormone-naive prostate cancer ("research concerning human diseases") received oral enzalutamide (Xtandi®) 160 mg/day.

Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?
Ja

BECAUSE
This research project included men aged 18 or older ("persons") with hormone-naive prostate cancer.

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Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?
Ja

BECAUSE
According to the study protocol, the investigator treated men ("persons") with hormone-naive prostate cancer with oral enzalutamide (Xtandi®) 160 mg/day ("health related intervention [therapeutic measure]"). These men were "prospectively assigned" to the intervention, and the study estimated the proportion of patients whose prostate-specific antigen had declined 80% or more by week 25 ("to investigate its effect on health").

Wird in der Studie ein Arzneimittel (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g Medizinprodukteverordnung (MepV) vom 1. Juli 2020) untersucht?
Ja

BECAUSE
This clinical trial investigated the effects of enzalutamide (Xtandi®) 160 mg/day ("medicinal products").

Ist das Arzneimittel in der Schweiz zugelassen?
Ja

BECAUSE
This clinical trial investigated the effects of enzalutamide (Xtandi®) 160 mg/day. Xtandi® is "authorised" for the market in Switzerland (approval number (Xtandi®): 63040 [Swissmedic]).

Wird in der Studie ein Placebo verwendet oder wird der Originalzustand des verwendeten Arzneimittels oder seine Verpackung verändert?
Nein

BECAUSE
This clinical trial investigated the effects of enzalutamide (Xtandi®) 160 mg/day. Xtandi® is "authorised" for the market in Switzerland, and is provided "as is". The medicinal product was provided in its original package but labelled with a trial-specific sticker (label). However, the label did not cover any pharmaceutically relevant information.

Wird das Arzneimittel in der Studie gemäss Fachinformation angewendet?
Nein

BECAUSE
This clinical trial investigated the effects of enzalutamide (Xtandi®) 160 mg/day in men aged 18 or older with hormone-naive prostate cancer, for whom hormone therapy was indicated and who had non-castration levels of testosterone. Enzalutamide (Xtandi®) was not given in combination with hormone therapy. Enzalutamide (Xtandi®) is approved in combination with luteinising hormone-releasing hormone analogues to treat patients with metastatic castration-resistant prostate cancer, who already received docetaxel therapy. Use of enzalutamide (Xtandi®) within this clinical trial does not correspond with approved uses.

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Wird von der Fachinformation nur in Bezug auf die Indikation oder die Dosierung abgewichen?
Ja

BECAUSE
This clinical trial investigated the effects of enzalutamide (Xtandi®) 160 mg/day in men aged 18 or older with hormone-naive prostate cancer, for whom hormone therapy was indicated and who had non-castration levels of testosterone. Xtandi® was not combined with hormone therapy. Xtandi® is approved in combination with luteinising hormone-releasing hormone analogues to treat patients with metastatic castration-resistant prostate cancer, who have already received docetaxel therapy. The use of Xtandi® in this clinical trial does deviates from the specifications in the Summary of Product Characteristics only in regards to required co-interventions, but not regarding indication or dosage.

Liegt die Indikation innerhalb derselben Krankheitsgruppe der ICD-10 Klassifizierung, wie sie in der Fachinformation aufgeführt ist (massgebend ist die mit dreistelligem Code definierte Krankheitsgruppe)?
Ja

BECAUSE
This clinical trial investigates the effects of enzalutamide (Xtandi®) 160 mg/day in men aged 18 or older with hormone-naive prostate cancer, for whom hormone therapy was indicated and who had non-castration levels of testosterone. Xtandi® is approved in combination with luteinising hormone-releasing hormone analogues to treat patients with metastatic castration-resistant prostate cancer, who have already received docetaxel therapy. Hormone-naive prostate cancer falls within the same ICD-10 group as the approved indication (metastatic castration-resistant prostate cancer, for those who have previously received docetaxel therapy C61: Malignant neoplasm of prostate).

Handelt es sich bei der Krankheit für die das Arzneimittel im klinischen Versuch angewendet wird um eine selbstlimitierende Krankheit?
Nein

BECAUSE
This clinical trial investigates the effects of enzalutamide (Xtandi®) 160 mg/day in men aged 18 or older with hormone-naive prostate cancer, for whom hormone therapy was indicated and who had non-castration levels of testosterone. Self-limiting diseases resolve spontaneously, with or without treatment. Untreated hormone-naive prostate cancer does not resolve spontaneously.

Entspricht die Anwendung einem medizinischen Standard, welcher als solches in einer nach international anerkannten Qualitätskriterien verfassten Leitlinie aufgeführt ist?
Ja

BECAUSE
This clinical trial investigates the effects of enzalutamide (Xtandi®) 160 mg/day in men aged 18 or older with hormone-naive prostate cancer, for whom hormone therapy was indicated and who had non-castration levels of testosterone. Xtandi® was not be given in combination with hormone therapy. Thus it does not comply with the intended use recommended by the European Association of Urology guidelines on prostate cancer (treatment guideline developed in accordance with international quality criteria).

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