# The Effect Of Enzalutamide on Oxycodone Metabolism in Men with Prostate Cancer

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23562

**Source**
NTR

**Brief title**
ENZYME

**Health condition**

Prostate cancer
Pain

### Sponsors and support

**Primary sponsor:** Deventer Hospital
**Source(s) of monetary or material Support:** Deventer Hospital, investigator initiated

### Intervention

### Outcome measures

#### Primary outcome

Difference in pharmacokinetics of oxycodone in the presence and absence of enzalutamide, expressed in maximum serum concentration (Cmax) of oxycodone.

#### Secondary outcome

Differences in pharmacokinetics of oxycodone in the presence and absence of enzalutamide, expressed in:
1. Maximum serum concentration (Cmax) of noroxycodone, oxymorphone and noroxymorphone;
2. Area under the serum concentration versus time curve from time zero to the time (t) corresponding to the last quantifiable concentration (AUC0-t) of oxycodone and its metabolites noroxycodone, oxymorphone and noroxymorphone;
3. Area under the concentration-time curve from time zero to infinity with extrapolation of the terminal phase (AUC0-∞) of oxycodone and its metabolites noroxycodone, oxymorphone and noroxymorphone;
4. Terminal half-life (t1/2) of oxycodone and its metabolites noroxycodone, oxymorphone and noroxymorphone.

# Study description

### Background summary

Rationale: Oxycodone is an opioid receptor agonist that is metabolized mainly in the liver by CYP3A4 and 2D6 enzymes. Enzalutamide is one of the next-generation endocrine agents used in patients with (nonmetastatic and metastatic) CRPC. Because enzalutamide is a strong inducer of CYP3A4, it is expected that enzalutamide will reduce the analgesic effects of oxycodone, which is also metabolised along this pathway. This could have an important impact on patients' pain-related quality of life and on the effective and safe use of oxycodone and enzalutamide.
Objective: To investigate the effect of enzalutamide on the pharmacokinetics (PK) of oxycodone following a single 15 mg dose of normal-release oxycodone in men with prostate cancer.
Study design: A prospective, open-label, two arm parallel study.
Study population: 24 males aged ≥ 18 years with prostate cancer treated with enzalutamide (arm 1) or not treated with enzalutamide (arm 2).
Intervention: Subjects will receive a single oral dose of normal-release oxycodone 15 mg.
Main study parameters/endpoints: Difference in pharmacokinetics of oxycodone in the presence and absence of enzalutamide, expressed in Cmax.

### Study objective

It is expected that enzalutamide will enhance the CYP3A4 mediated metabolism and decrease the plasmalavels of oxycodone.

### Study design

Six time points (t=1, 1.5, 2, 4, 6, 8h) after oxycodone intake.

**Intervention**

Oxycodone normal-release 15 mg single oral dose in the presence (experimental) and absence (control) of enzalutamide

# Contacts

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# Eligibility criteria

## Inclusion criteria

 Males aged ≥ 18 years;
 Diagnosed prostate cancer;
 Treated with enzalutamide 160 mg once daily for 40 days (arm 1)

## Exclusion criteria

 known metastases in the liver that would affect drug metabolism;
 Child-Pugh classification B or C that would affect drug metabolism;
 known moderate-severe renal dysfunction (GFR <60 ml/min/1.73m2) that would affect drug metabolism;
 gastrointestinal disorders that would potentially alter absorption;
 previous gastric bypass or gastric band surgery;
 known allergy, hypersensitivity or intolerance to normal-release oxycodone;
 a history of drug abuse or treatment for abuse;
 dose-reduction or ≥5 successive days of treatment interruption of enzalutamide within 40 days prior to the study day (arm 1);
 treatment with enzalutamide within 40 days prior to the study day (arm 2);
 use of oxycodone normal-release within 24 hour prior to oxycodone intake or use of

oxycodone extended-release within 2 days prior to oxycodone intake;
 use of other medication that would affect oxycodone metabolism, see section 5.2 and appendix B;
 use of other medication that would affect enzalutamide metabolism, see section 5.2 and appendix B (arm 1).

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-04-2021 |
| Enrollment: | 24 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Not applicable

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|---|---|
| Application type: | Not applicable |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL9077 |
| CCMO | NL.75669.075.20 |

# Study results