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# A multi-centre, non-interventional study of relugolix in patients with advanced hormone-sensitive prostate cancer

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| **Submission date**<br>24/03/2026 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>30/03/2026 | **Overall study status**<br>Ongoing | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>30/03/2026 | **Condition category**<br>Cancer | [_] Individual participant data<br>[X] Record updated in last year |

## Plain English summary of protocol

Background and study aims
This study looks at how well a medicine called relugolix works for people with advanced hormone sensitive prostate cancer when used as part of their usual clinical care. It is an observational study, which means researchers do not change or add any treatments. Instead, they collect information from routine medical visits to understand how patients respond to relugolix in real life.

Who can participate?
Men aged 18 years or older who have been diagnosed with prostate cancer can take part if their doctor has already decided that relugolix is the right treatment for them. Participants must be starting relugolix for the first time and planning to stay on this treatment for at least twelve months. People who have had surgical castration, have used relugolix before, or cannot give informed consent cannot join the study.

What does the study involve?
Taking part does not change the care or treatment a patient receives. All clinic visits, tests, and assessments happen as part of normal medical care. There are no extra appointments or procedures required for the study. Researchers collect information from medical records for up to one year after a participant signs the consent form. This includes medical history, test results, details of prostate cancer treatment, any side effects, and how the disease changes over time.

What are the possible benefits and risks of participating?
Because the study does not alter treatment, there are no direct medical benefits from taking part. However, the information collected may help improve understanding of how relugolix works in everyday clinical practice, which could benefit future patients. There are no additional risks beyond those of standard prostate cancer care, as no experimental treatments or extra tests are required.

Where is the study run from?
The study is taking place in several hospitals across Europe, including sites in England, France,

Germany, Ireland, Italy, Romania, and Spain. In England, participating centres include Royal Cornwall Hospital in Truro, Diana Princess of Wales Hospital in Grimsby, and Westmorland General Hospital in Kendal.

When is the study starting and how long is it expected to run for?
November 2024 to November 2027.

Who is funding the study?
The study is funded by Accord Healthcare.

Who is the main contact?
Professor Alison Birtle at Royal Lancaster Infirmary, alison.birtle@lthtr.nhs.uk

# Contact information

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# Additional identifiers

### Integrated Research Application System (IRAS)
344820

# Study information

### Scientific Title
RENAISSANCE - A multi-centre, non-interventional study of RElugolix as aNdrogen-deprivAtion therapy In patientS with advanced hormone-Sensitive prostate cANCEr

### Acronym
RENAISSANCE

### Study objectives

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 23/09/2024, East Midlands - Nottingham 2 Research Ethics Committee (Health Research Authority Redman Place, Stratford, E20 1JQ, United Kingdom; +44 207 104 8009; nottingham2.rec@hra.nhs.uk), ref: 24/EM/0214

### Primary study design
Observational

### Secondary study design
Cohort study

### Study type(s)

### Health condition(s) or problem(s) studied
Prostate cancer

### Interventions
The participants' relugolix dose and regime will already be decided by their doctor and participating in this study will not alter this in any way.

Patients will undergo clinical assessments and receive standard medical care as determined by the patient’s investigator in a real-world practice setting. Patients will not receive any experimental intervention or treatment as part of their participation in this study.

No mandatory visits, tests, or clinical assessments are required for this study. All visits will be scheduled and conducted according to the clinical site’s routine clinical practice. Data will be extracted from the medical records

Data will be collected up to 52 weeks after the consent form is signed. The following data will be collected:
· Standard clinical review (medical and surgical history)
· Baseline clinical characteristics, including disease stage, medical history related to the disease, routine imagery and laboratory results
· Information related to the treatment (date of initiation, reason, posology, interruption with the duration and the reason, date of discontinuation and reason)
· Disease evolution during the follow-up
· Concomitant medications for prostate cancer
· Review of any unwanted side effects

### Intervention Type
Other

### Primary outcome(s)
1. Disease evolution measured using disease state, TNM, PSA level, testosterone, prostatectomy details, radiotherapy details, details of other local interventions at baseline, 6m and end of study (12m)

### Key secondary outcome(s)
1. Demographics and baseline clinical characteristics measured using age, country, ethnicity, body weight, ECOG, baseline disease stage, location of metastases, baseline PSA level, baseline testosterone, PSA level, testosterone level, prostatectomy, radiotherapy , other local intervention information, prior ADT, con meds for PCa, CV risks at baseline

2. Treatment persistence including reasons for changes to and from relugolix treatment measured using details of relugolix treatment (date of treatment initiation, daily dose, treatment interruptions, if applicable date & reason for discontinuation at baseline, 6m and end of study (12m)

3. Prostate cancer history/other prostate cancer treatment measured using name of concomitant medications, date of initiation, daily does and date of discontinuation at baseline, 6m and end of study (12m)

4. Disease evolution measured using disease state, location of metastases, TNM, PSA level, testosterone level, prostatectomy, radiotherapy , other local intervention information at 6m and end of study (12m)

5. Safety measured using all adverse events at 6m and end of study (12m)

### Completion date
01/11/2027

## Eligibility

### Key inclusion criteria

1. Patient who had voluntarily signed and dated the informed consent form
2. Male patients aged 18 years or older
3. Patients who had histologically or cytologically confirmed diagnosis of adenocarcinoma of the prostate described in the
patient’s file
4. Patients deemed eligible for androgen-deprivation therapy with relugolix prescribed as part of standard clinical practice.
5. Patient who has agreed with the investigator the initiation of relugolix, per the investigator's decision, prior to enrolment into the study
6. Intended duration of androgen-deprivation therapy of at least twelve months

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
99 Years

### Sex
Male

### Total final enrolment
0

### Key exclusion criteria
1. Patient unable to provide informed consent
2. History of surgical castration
3. Intended duration of androgen-deprivation therapy of less than 12 months
4. Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the product information
5. Patient who has already received or is currently receiving relugolix
6. Participants who are not treated in line with current Summary of Product Characteristics for relugolix

### Date of first enrolment
06/11/2024

### Date of final enrolment
01/11/2026

## Locations

### Countries of recruitment
United Kingdom

England

France

Germany

Ireland

Italy

Romania

Spain

**Study participating centre**
**Royal Cornwall Hospitals NHS Trust**
Royal Cornwall Hospital
Treliske
Truro
England
TR1 3LJ

**Study participating centre**
**Northern Lincolnshire and Goole NHS Foundation Trust**
Diana Princess of Wales Hospital
Scartho Road
Grimsby
England
DN33 2BA

**Study participating centre**
**University Hospitals of Morecambe Bay NHS Foundation Trust**
Westmorland General Hospital
Burton Road
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LA9 7RG

# Sponsor information

**Organisation**
Accord healthcare

# Funder(s)

**Funder type**

**Funder Name**
Accord Healthcare

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not expected to be made available