Comparative effectiveness and safety in patients with prostate cancer who received radical prostatectomy vs. radiotherapy: target trial emulation

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000808

Study ID

1000000808

DARWIN EU® study

No

Study countries

Estonia

Germany

United Kingdom

Study description

This study aims to compare the effectiveness and safety outcomes in patients with early stage prostate cancer who received radical prostatectomy or radiotherapy using the target trial emulation framework. The study populations of interest include those restricted to the emulated trial eligibility criteria, and the broader population in routine clinical practice.

Study status

Ongoing

Research institutions and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Actual: 01/10/2021

Study start date
Actual: 01/10/2024

Data analysis start date
Actual: 01/01/2025

Date of final study report
Planned: 31/08/2026

Sources of funding

- EU institutional research programme

More details on funding

OPTIMA is funded through the IMI2 Joint Undertaking and is listed under grant agreement No. 101034347. IMI2 receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations (EFPIA). IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.

Study protocol

OPTIMA_prostateCa_TTE_protocol.pdf (334.9 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Medical procedure

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

An international network cohort study using data mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). The study will use a new user design and compare patients who received radical prostatectomy to those who received radiotherapy for prostate cancer.

Main study objective:

1. To estimate the comparative effectiveness and safety of surgical versus radiological treatment of prostate cancer in the target trial population
2. To estimate the comparative effectiveness and safety of surgical versus radiological treatment of prostate cancer in the real world data population

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Prostate cancer

Population studied

Short description of the study population

Adult men aged 18+ years on the date of receiving first radical prostatectomy or radiotherapy (index date)

• At least 1 year of observation pre index date

• No prior treatment for prostate malignancy

• Clinically localised prostate cancer (T1-T2, NX, M0) or Stage 1-2 diagnosed with no M1 or Stage 3-4 diagnosis

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Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Study design details

Setting

Additional criteria for target trial population

• Clinically localised prostate cancer (T1-T2, NX, M0) or Stage 1-2 diagnosed in the 6 months pre index date

• Age 50-69 years on the date of PCa diagnosis

• PSA in the range 3.0-19.99 ng/ml in the year pre-index

• No concomitant or past malignancies (other than a small treated skin cancer)

• No serious cardiac or respiratory problems in the previous 12 months of the index date, i.e. stroke, MI, heart failure, COPD
• No kidney dialyses or transplantation pre-index date
• No bilateral hip replacement pre-index date

Comparators

Radical prostatectomy vs radiotherapy (external beam radiotherapy, brachytherapy)

Outcomes

Mortality (all-cause and cancer specific), disease progression (PSA biochemical recurrence, metastasis, initiation of long term hormone therapy), treatment complications (rectal/bowel injury/symptoms, sexual dysfunction, urethral stricture, lower urinary tract symptoms and treatment, incontinence and obstruction), depression and psychological state, metabolic syndrome, cardiovascular outcomes

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Data analysis plan

This study will follow the target trial emulation framework, using the ProtecT clinical trial as a benchmark. Propensity score methods will be used to adjust for confounding. Cox regression models will be used to estimate the hazard ratios of the outcomes.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data source(s), other

German Cancer Society

Estonian Cancer

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

5.4

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes