Association between androgen deprivation therapy and excess mortality after covid-19 in patients with prostate cancer

First published: 07/08/2020

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Study Finalised

Administrative details

EU PAS number

EUPAS36621

Study ID

43583

DARWIN EU® study

No

Study countries

Sweden

Study description

Men appear to have an approximately 50% higher risk for infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) than women, also when adjusted for other risk factors. Male sex also predicts a 50-60% increased risk for critical care admission and/or death in covid-19. One proposed mechanism is that androgen signaling facilitates entry of SARS-CoV-2 into host cells. Internalization of the SARS-Cov-2 virus relies on proteases such as the Transmembrane Protease Serine 2 (TMPRSS2). The regulation of TMPRSS2 expression is androgen-dependent, suggesting that androgen deprivation therapy (ADT) could potentially have a protective effect against covid-19. More than a dozen clinical trials are being planned or are already ongoing to evaluate the effects of ADT in men with Covid-19. This rapid progression from hypothesis to clinical trials also raises concern. ADT is associated with an increased risk of cardiovascular disease (CVD) in men with prostate cancer. Even short-term ADT may increase the risk. The benefit-risk ratio for exposing men with covid-19 could therefore be supported by further observational data, indicating that ADT in men with prostate cancer confers protection against severe covid-19. The aim of this study was to estimate the impact of ADT on excess mortality in men with prostate cancer during the initial peak of covid-19 in the spring of 2020 compared to previous years.

Study status

Finalised

Contact details

Study institution contact

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Primary lead investigator

Rolf Gedeborg

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/07/2020

Actual: 03/07/2020

Study start date

Planned: 25/06/2020

Actual: 25/06/2020

Date of final study report

Planned: 30/11/2020

Actual: 08/10/2021

Sources of funding

- Other

More details on funding

Swedish Research Council

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study was to estimate the impact of ADT on excess mortality in men with prostate cancer during the initial peak of covid-19 in the spring of

2020 compared to previous years.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L02BB03) bicalutamide

bicalutamide

(L02AE) Gonadotropin releasing hormone analogues

Gonadotropin releasing hormone analogues

(H01CC) Anti-gonadotropin-releasing hormones

Anti-gonadotropin-releasing hormones

(L02BB04) enzalutamide

enzalutamide

(L02BX03) abiraterone

abiraterone

Medical condition to be studied

COVID-19 treatment

Prostate cancer metastatic

Population studied

Short description of the study population

Men with prostate cancer were identified in The National Prostate Cancer Register (NPCR) of Sweden, which since 1998 captures 98% of all cases of prostate cancer in Sweden as compared to the Swedish Cancer Register to which registration is mandatory.
In PCBaSe an open cohort was defined with men with prevalent prostate cancer alive on 1 March 2020 and similar subsets for corresponding months in 2015–2019. Men from three regions in which GnRH agonists were provided directly from the hospital without prescription were excluded.

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)

Special population of interest

Other

Special population of interest, other

Prostate cancer patients

Estimated number of subjects

720.000

Study design details

Data analysis plan

In order to avoid misclassification of cause of death, we will also compare excess mortality among men on ADT vs. men not on ADT regardless of cause of death. By use of Poisson regression we will compare the number of deaths during the pandemic with number of deaths in corresponding time periods in the previous five years. We will take Pca risk category, age, and comorbidity into account.

Documents

Study results

Gedeborg 2021 PLOS Excess mortality.pdf (877.66 KB)

Study publications

Gedeborg R, Styrke J, Loeb S, Garmo H, Stattin P (2021) Androgen deprivation th...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

The Swedish prescribed drug register

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No