

DISCOVER study: Detecting Increased Susceptibility for Cancer in relatives by Offering genetic Variant Evaluation as Regular health care: prostate cancer

Published: 20-07-2021

Last updated: 19-11-2023

Mainstreaming of germline genetic tests in regular healthcare is feasible for healthcare professionals and acceptable for both patients and healthcare professionals

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON21534

Source

Nationaal Trial Register

Brief title

DISCOVER

Condition

- Reproductive neoplasms male malignant and unspecified

Health condition

Prostate cancer

Research involving

Human

Sponsors and support

Primary sponsor: University Medical Center Utrecht, department of Genetics

Source(s) of monetary or material Support: KWF Dutch Cancer Society

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Experience of healthcare professionals and patients with the mainstreaming pathway in metastatic prostate cancer

Secondary outcome

Efficacy of the mainstreaming pathway in metastatic prostate cancer

Study description

Background summary

The use of germline genetic tests in patients with prostate cancer is increasing. International guidelines recommend to consider a germline genetic test in patients with metastatic prostate cancer. To improve access to genetic testing in patients with metastatic prostate cancer, mainstreaming of germline genetic testing is implemented in multiple hospitals in the Netherlands. In the mainstreaming pathway urologists, oncologists and nurse specialists discuss and order germline genetic tests themselves in patients with stage TxNxM1 prostate cancer. These healthcare professionals will be trained with the use of an online training module. The online training module can be completed in one hour and describes background knowledge and key information for counseling patients with metastatic prostate cancer. The aim of this study is to assess the experiences of patients and non-genetic healthcare professionals with this pathway with the use of questionnaires. Besides this, the efficacy of the mainstreaming pathway will be determined, based on the uptake of germline genetic testing, the diagnostic yield and the number of families with a germline variant that can yearly be identified with this pathway.

Study objective

Mainstreaming of germline genetic tests in regular healthcare is feasible for healthcare

professionals and acceptable for both patients and healthcare professionals

Study design

Patients: T0 directly after healthcare professional discussed and ordered germline genetic test. T1 4 weeks after receiving genetic test result. T2 6 months after receiving genetic test result. Healthcare professionals: T0 before attending online training module. T1 3 months after attending online training module. T2 9 months after attending online training module.

Intervention

Mainstream germline genetic testing

Contacts

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Eligibility criteria

Age

Adults (18-64 years)

Adults (18-64 years)

Elderly (65 years and older)

Elderly (65 years and older)

Inclusion criteria

1. Men with prostate cancer, stage TxNxM1; 2. Germline genetic test is discussed and ordered by non-genetic healthcare professional

Exclusion criteria

1. Tumor DNA-test; 2. Pretest counseling by clinical geneticist or genetic counselor; 3. Unable to understand, speak and write Dutch language

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2021
Enrollment:	800
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable	
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	NL9617
Other	METC Utrecht : 20/577

Study results