

Identifying the Need of Discussing Infertility Concerns Affecting Testicular cancer patients; an Evaluation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON42094

Source

ToetsingOnline

Brief title

INDICATE

Condition

- Reproductive neoplasms male malignant and unspecified
- Sexual function and fertility disorders

Synonym

testis cancer

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Bontius stichting Doelfonds Urologie;LUF

Intervention

Keyword: counseling, fertility, testis cancer

Outcome measures

Primary outcome

The study measures the quality of the discussion on the risk of an impaired fertility, the advice regarding cryopreservation with health care providers. Furthermore, the provision of information on testicular implants is assessed.

Secondary outcome

In which ways information about impaired fertility and cryopreservation is obtained (written material, websites, relatives etc.) The success of ejaculation when attempting cryopreservation. The moment at which cryopreservation took place in relation to the treatment. The influence of non-reimbursed costs of cryopreservation. If patients succeed in getting children, in what way (naturally or artificial fertilization) or why succes was forthcoming.

Study description

Background summary

Patients with treated testicular cancer (TC) risk an impaired fertility. Since the high life expectancy and the onset in a young and reproductive age, quality of life including fertility and masculinity are of major concern when treating TC patients. In a short period of time after discovering cancer, patients receive orchiectomy and eventual adjuvant therapy might follow, depending on staging of the disease. In this brief period the patient will be stricken with many questions about his health and future. Patients should be informed about the risk of a impaired fertility as result of the treatment and the possibility

of cryopreservation as soon as possible. In this way, the patient is able to make well-considered decisions about his fertility and cryopreservation of his sperm. Furthermore, patients should be informed about the possibility of placing an testicular implant.

Study objective

This study is designed to determine quality of care for the discussion of fertility concerns and cryopreservation after diagnosis and treatment for TC. The consult with health care providers where patients are informed about the risk of impaired fertility plays a central role. Furthermore, we will evaluate the way patients obtain information and the influence on subsequent choices about cryopreservation. Also, the experience of cryopreservation is addressed, as well as which health care provider and which context would have the preference of the patient for discussion fertility concerns. Last, the provision of information on testicular implants is assessed. This survey will contribute to improvements of healthcare so patients can make the right choices after diagnosed cancer. In this way unexpected fertility and embarrassment problems later in life can be diminished.

Study design

A cross-sectional questionnaire survey will be conducted among patients with testicular cancer who are or were treated in the LUMC in the Netherlands (n=625). The questionnaire was designed by the authors, based on study aim and a review of the literature in the area. A patient panel of the Dutch Testicular Cancer Society piloted the questionnaire. Suitable patients are obtained through the local cancer registry of the LUMC and will receive an information letter and a included consent. After agreeing to participate, patients will receive the questionnaire by mail. The questionnaire can be completed at home (approximately 20 minutes) and will be sent back by post. Data will be processed and analysed anonymously.

Study burden and risks

The questionnaire could be confronting and may raise fertility concerns, depending on the patient's knowledge on impaired fertility and the patient's attitude towards fertility. This risk will be constrained as much as possible by sending an information letter in advance. In this way ambiguities on the risk of a impaired fertility in relation to the treatment of testicular cancer are clarified.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Medical history includes a testiscarcinoma, diagnosed after the age of 18 years

Exclusion criteria

Mental incompetence

Under 18 years

Unfamiliar with the Dutch language;(Before the mailing takes place, patients who are deceased will be removed from the sample).

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 07-10-2015

Enrollment: 625

Type: Actual

Ethics review

Approved WMO

Date: 10-12-2015

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL52346.058.15