Cryopreservation of prepubertal testicular tissue for future autologous transplantation of spermatogonial stem cells: preserving fertility in young boys with cancer

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To preserve testicular tissue of young boys with cancer for possible autologous transplantation in the future if infertility has become apparent.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON39737

Source
ToetsingOnline

Brief title
Cryopreservation of spermatogonial stem cells in childhood cancer patients

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Sexual function and fertility disorders

Synonym
Cancer

Research involving
Sex cells

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw (programma Translationeel Adult Stamcel Onderzoek),Subsidie van Stichting Kinderen met Kanker (Kika)

Intervention

Keyword: Cancer, Chemotherapy, Infertility, Long term side effects, Spermatogenesis, Spermatogonial Stem Cells

Outcome measures

Primary outcome

Successful sampling and storage of testicular tissue (cryosurvival of SSCs,

ability to propagate SSCs in vitro).

Secondary outcome

Long-term follow-up of possible side-effects of the testicular biopsy in the

boy (local defects, endocrine and exocrine function of the remaining testis),

post-pubertal fertility (as determined by semen analysis).

Study description

Background summary

Modern cancer treatment allows the majority of prepubertal boys to survive their malignancy. Unfortunately, many of these boys treated with high dose chemotherapy will become infertile (Brougham & Wallace, 2005;van den Berg et al, 2004). Currently, in prepubertal boys diagnosed with cancer there are no means to preserve their reproductive potential, which contrasts with adolescents and adults, for whom cryopreservation of semen prior to the start of chemotherapy is available and widely used.
We have pioneered cryopreservation of testicular tissue and subsequent autotransplantation of spermatogonial stem cells (SSCs) in animal models(Izadyar et al, 2003) and have recently succeeded in cryopreserving and propagating human SSCs from adult men (Sadri Ardekani et al., submitted). We estimate that we will be ready for clinically applying SSC autotransplantation within the next decade. Given the long time interval between cryopreserving

testicular tissue in prepubertal boys and possibly using this tissue for autotransplantation when these boys have become adults and have been diagnosed with infertility (most likely at least 15 years), we feel it is now time to start with cryopreservation of testicular tissue of young boys with cancer.

Study objective

To preserve testicular tissue of young boys with cancer for possible autologous transplantation in the future if infertility has become apparent.

Study design

Prospective cohort study in prepubertal boys.

Study burden and risks

Under general anaesthesia a testicular biopsy will be taken; provided that a signed informed consent is obtained from both parents and, if 12 years of age or older, the prepubertal boy. Scheduling the testicular biopsy at the moment of performing pre-treatment procedures minimizes the burden for the patient and will not postpone start of therapy. To minimize the risk of the biopsy, the procedure will only be done on one testis under the condition that there is no history of testicular torsion or cryptorchidism. The biopsy will be approximately 0.6-0.8 ml in size and will never exceed 50% of one testis. The microsurgical techniques will ensure that substantial loss of testicular tissue does not occur. Since anti-cancer treatment has not yet started at the moment of biopsy, the patient*s immune system will not be compromised and the risk of infection is minimal. In solid tumours bleeding is unlikely to be a major problem since thrombocyte numbers and function are generally normal in these patients. In leukaemia patients thrombocytopenia does occur at the moment of diagnosis, but haemostasis is routinely secured by thrombocyte transfusion in view of the other procedure performed during the same session. As a result no additional thrombocyte transfusions are expected to be necessary. Follow-up will be done at the moment of follow-up for the malignancy. No additional hospital visits are foreseen in conjunction with this proposal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Young patients with cancer (up till 15 years of age)
- Scheduled to undergo cytotoxic treatment with risk of future infertility
- Unable to produce spermatozoa containing semen

Exclusion criteria

- Malignancies located in the testis (suspicion of metastases of for example lymphomas)
- history of bilateral cryptorchidism or testicular torsion
- ability to ejaculate vital spermatozoa.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	07-09-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	03-06-2014
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL27690.000.09