Biobanking of testicular biopsies from azoospermic men undergoing testicular sperm extraction (TESE)

Published: 30-01-2017
Last updated: 30-01-2025

Biobanking of a testis biopsy from men with azoospermia who undergo a TESE procedure to allow investigation for understanding the etiology of male infertility, research about normal and aberrant male gamete formation in its natural environment of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Testicular and epididymal disorders
Study type	Observational invasive

Summary

ID

NL-OMON43336

Source
ToetsingOnline

Brief title
Biobanking of testicular biopsies

Condition

- Testicular and epididymal disorders

Synonym
azoospermia, male infertility

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Azoospermia, Biobanking, TESE, testicular tissue

Outcome measures

Primary outcome

To biobank testis biopsies in order to investigate all aspects of the process

of human sperm production and defects in sperm production in patients with a

sever male factor.

Secondary outcome

- To understand the cellular and molecular aspects of male infertility

- To develop novel treatment strategies for male infertility

Study description

Background summary

Subfertility affects approximately 15% of all couples, and a severe male factor is identified in 17% of these couples. The etiology of a severe male factor remains largely unknown. Couples with a severe male factor can resort to intracytoplasmic sperm injection (ICSI), with either ejaculated spermatozoa (in case of oligozoospermia) or surgically retrieved testicular spermatozoa (TESE) (in case of azoospermia) to generate biologically own children. However, currently there is no direct treatment for men with azoospermia or oligozoospermia. However to get a better understanding about the etiology of male infertility, research about normal and aberrant male gamete formation in its natural environment of the testis is necessary to pave the way to establish future interventions.

Study objective

Biobanking of a testis biopsy from men with azoospermia who undergo a TESE procedure to allow investigation for understanding the etiology of male infertility, research about normal and aberrant male gamete formation in its natural environment of the testis is necessary to pave the way to establish future interventions.

Study design

Men with azoospermia that have a wish for biologically own children can opt to undergo a TESE procedure to obtain testicular sperm in order to fertilize an oocyte during a subsequent IVF procedure. From those infertile patients who undergo a TESE procedure, we like to obtain an additional testis biopsy with informed consent for storage in the 'AMC Biobank Reproduction And Development'.

Study burden and risks

Taking an additional biopsy will not do any harm to the remaining testis or has consequences for the health of the men as this additional biopsy is taken during the standard TESE procedure.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

all adult men ondergoing TESE procedure.

Exclusion criteria

- HIV positive men
- patients who do not want to be informed in case of an unexpected negative finding related to a treatable or preventable disease that is clinically relevant for this men or his family.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	1500
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-01-2017
Application type:	First submission
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	NL58218.000.16