Does treatment of a varicocele in subfertile men result in more spontaneous pregnancies?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21167

Source
NTR

Brief title
Varicocele trial

Health condition

Varicocele and male subfertility

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: No external funding.

Intervention

Outcome measures

Primary outcome

Primary endpoint is spontaneous pregnancy within the 1 year follow-up period in both groups.

Secondary outcome

Secundairy endpoints are improvement of semen in both groups and predictive factors for a spontaneous pregnancy.

Study description

Background summary

Varicocele is a physical abnormality present in 10-15% of the adult male population. It is more common in men of infertile marriages, affecting 25-30% of those with abnormal semen analysis. The exact association between reduced male fertility and varicocele is unknown, but analysis of the WHO data clearly indicates that varicocele is related to semen abnormalities, decreased testicular volume and decline in Leydig cell function. Five prospective randomised studies of varicocele treatment in adults gave conflicting results, the largest of them indicating benefit (WHO-study, Hargreave et.al.).

We perform a prospective randomised trial on varicocele treatment in oligospermic men, comparing treatment to watchful waiting. 130 couples with an infertility duration of at least 1 year, are to be randomised for treatment or no treatment. All varicoceles will be confirmed by ultrasound investigation of the scrotum. Men with no other abnormalities than a varicocele and a subnormal sperm count according to the WHO-guidelines for semen analysis are included, excluding men with azoospermia. After 1 year of follow-up the couples can choose for either artificial reproductive techniques or (delayed) varicocele repair.

Study objective

Early treatment of a clinical varicocele in subfertile men results in more spontaneaous pregnancies as compared to no treatment.

Study design

1. Primary outcome: 1 year;

2. Secondary outcome: 3 and 6 months.

Intervention

The treatment group wil have a varicocele repair by surgery or embolisation with a follow-up of 1 year. The controls will have no treatment and a follow-up of 1 year.

Contacts

Public
Erasmus MC
P.O. Box 2040
G.R. Dohle
Rotterdam 3000 CA
The Netherlands
+31-10-7033095
Scientific
Erasmus MC
P.O. Box 2040
G.R. Dohle
Rotterdam 3000 CA
The Netherlands
+31-10-7033095

Eligibility criteria

Inclusion criteria

1. Clinical varicocele grade 1-3;

2. Male subfertility as confirmed by the results of two abnormal semen analyses;

3. Male age 20-60;

4. Female partner < 36 years of age and without any obvious fertility problem;

5. Infertility duration > 1 year.

Exclusion criteria

1. Azoospermia;

2. Normal semen analysis;

3. Other male infertility factor than varicocele;

4. Femal factor for the infertility.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-1998
Enrollment:	130
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-06-2009
Application type:	First submission

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	NL1727
NTR-old	NTR1837
Other	MEC ErasmusMC : 139.255/1996/1
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A