Does the time between the production of semen and Intra-Uterine Insemination has an impact on pregnancy rates? A prospective randomized clinical trail.

Published: 07-11-2011
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To evaluate if the pregnancy rate, number of ongoing pregnancies and the number of live births after IUI increases as the time between the production of semen and the IUI is shortened.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45103

Source
ToetsingOnline

Brief title
Short-long interval semen production-IUI (KLIPSI)

Condition

- Other condition

Synonym
insertion of sperm into the womb, Intrauterine insemination

Health condition

subfertiliteit

Research involving

Human

Sponsors and support

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

Intervention

Keyword: interval semen production-IUI, IUI, pregnancy rates

Outcome measures

Primary outcome

Ongoing pregnancy rate per patient couple (positive fetal cardiac activity 10

weeks after IUI).

Secondary outcome

Clinical pregnancy rate per IUI cycle (HCG> 50 IU /l at 16 days after IUI).

Ongoing pregnancy rate per IUI cycle (positive fetal cardiac activity 10 weeks

after IUI).

Percentage multiple pregnancies

Percentage biochemical pregnancies and abortions

Percentage/number of live births

Study description

Background summary

The ongoing pregnancy rate after IUI in VUmc has been in recent years about 7 to 8%. We would like to improve the ongoing pregnancy rate. Therefore a literature study was done to see if there were differences in approach that could lead to a better ongoing pregnancy rate. We found an article describing the method quite different from the standard VUmc method. This different approach resulted in much higher pregnancy outcomes (13-55%).

Study objective

To evaluate if the pregnancy rate, number of ongoing pregnancies and the number of live births after IUI increases as the time between the production of semen and the IUI is shortened.

Study design

Prospective randomised controlled clinical trial.

Intervention

Patients are inseminated approximately 3-4 hours after the production of semen (Group I, current practice VUmc) or patients are inseminated approximately 75 minutes after the production of semen (Group II, intervention group).

Study burden and risks

All patients receive a standard IUI treatment. There are no risks associated with participation in this study. Only the time interval between the production of semen and the IUI is changed.

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

Patients who start their first IUI treatment. All subsequent cycles fall within this study.
Patients who start a new IUI treatment after an ongoing pregnancy.
Both IUI performed in a natural cycle and stimulated cycles fall within this study.
Patients with well-adjusted, non-endocrine hormonal pathology fall within this study.

Exclusion criteria

Patients who have IUI with donorsemen.
Patients in which the semen was obtained in a different way than masturbation (bladder irrigation, electrical stimulation).
Patients who have less than 0.5 million progressive motile sperm left over after work-up of semen.
Patients with polycystic ovarian syndrome (PCOS).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-02-2012
Enrollment:	254
Type:	Actual

Ethics review

Approved WMO Date:	07-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL37363.029.11