A novel, simple method to obtain monofollicular punctates and the corresponding oocytes during oocyte pick ups for IVF or IVF/ICSI

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The objective of this study is to prove that the number of oocytes and the quality of embryos obtained from these oocytes harvested with this new needle is comparable with the number of oocytes and quality of embryos obtained from oocytes harvested...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33235

Source
ToetsingOnline

Brief title
Monofollicular IVF punctates

Condition

- Other condition

Synonym
infertility, IVF

Health condition

onvruchtbaarheid

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: unrestricted fund ScheringPlough/Merck Serono

Intervention

Keyword: follicle, follicle fluid, IVF, oocyte

Outcome measures

Primary outcome

Primary study parameter:

The yield of oocytes per number of follicles> 10mm, monofollicular versus

pooled

Secondary outcome

Secundary study parameters

% fertilisation, monofollicular versus pooled.

% top quality embryo*s monofollicular versus pooled.

Mean diameter of the 1st monofollicular punctured follicle related to the

obtained amount of follicular fluid..

Study description

Background summary

In routine IVF treatments, pre-ovulatory follicles are punctuated under different circumstances. In the early days of IVF, the laparoscopic (Steptoe and Edwards 1970) and the transvescical (Robertson, Picker et al. 1986) method was used, while today all oocyte retrievals are being done vaginally (Kemeter and Feichtinger 1986). Some clinics routinely flush the follicles (Bagtharia and Haloob 2005) and others don*t. In most cases the obtained punctate will be

pooled, ie fluid and the oocytes from different follicles will be collected in one larger bottle or tube, as the follicles will be punctuated one after another without withdrawing the needle again and again. This method is obviously simple and fast. However, today, an increasing interest exists in different parameters regarding the micro environment of the oocyte in relation to oocyte and embryo quality, implantation and pregnancy outcome (Boxmeer, Brouns et al. 2008), (Rosen, Shen et al. 2007). Therefore, some authors have published data after retrieving mono-follicular punctuates (Boxmeer, Brouns et al. 2008).
Different methods exist to obtain a mono-follicular punctate. A single follicle can be punctured and the fluid from this single follicle can be collected in a separate bottle or tube. The bottle will be replaced (without withdrawing the needle from the ovary) and the next follicle will be punctured. The disadvantage of this method is that a relatively large amount of the follicular fluid of the first follicle will not be collected in the separate first sample but will stay behind in the tubing and the needle of the collecting system. This fluid will be collected during puncturing the next follicle. Therefore concentrations of different contents of the fluid of a single follicle can only be assessed from the first sample, as the consecutive samples will be mixed. Moreover, as a relatively large amount of fluid remains in the tubing and needle, the chance that the corresponding oocyte is present in the separate first sample is relatively low. To overcome these problems it is also possible to withdraw the needle from the ovary and change bottles after puncturing every single follicle. This will obviously increase duration of the procedure, increase pain and discomfort for the patients and probably cause more tissue damage in the ovaries (El-Shawarby, Margara et al. 2004).
In order to be able to collect mono follicular samples together with the corresponding oocyte effectively a new oocyte pick up needle was designed and manufactured (Gynotec, Malden, The Netherlands). The aim of this study examine the effectivity and safety of the use of this new needle.

Study objective

The objective of this study is to prove that the number of oocytes and the quality of embryos obtained from these oocytes harvested with this new needle is comparable with the number of oocytes and quality of embryos obtained from oocytes harvested with a conventional needle.

Study design

All couples who will be starting an IVF or ICSI treatment in the ErasmusMC are being invited for an information evening (in which the entire treatment as well as the laboratory procedures will be explained). Within weeks after this evening an intake with these couples willl take place. Thereafter the iVF treatment will actually start.
During the information evening, the researcher will present a couple of slides

regarding the study. Moreover, couples will receive the patient information form. During intake, the fertilitity doctor will ask the couple to participate. Couples can get additional information if needed at that moment. This is the moment to sign the informed consent.
If on the day of ovum pick up a patient turns out to be elegible, and if she has signed the informed consent, randomisation can take place. The randomisation dictates which ovary will be punctured monofillicular and which pooled. The right ovary will allways be punctured first. All ovum pick ups will be performed by the same doctor (the researcher)

Study burden and risks

As the efficacy of this needle will be tested during a procudere which patients will undergo during their IVF treatment, they do not undergo an extra intervention. Therefore, both burden and risk are comparable for participants and non participants. The duration of the oocyte pick pick up could possibly be slightly increased due to the increased changing of the bottles.
Theorettically, the new needle could give a lower yield in oocytes. However, as in one procedure both the conventional and the new needle will be used, the risk of reduced pregnancy chances can be considered as low.

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

on the day of oocyt retrieval at least 2 follicles per ovarium, and a maximum of 10 follicles per ovarium should be present prior to randomisation

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-03-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	03-02-2010

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	NL26347.000.09