Relation between women's nutrition, serum and follicular fluid composition and modified natural cycle IVF outcome parameters

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

Summary

ID

NL-OMON40567

Source
ToetsingOnline

Brief title
Oocyte environment and IVF

Condition

- Other condition

Synonym
fertility problems, subfertility

Health condition

subfertiliteit

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Unrestricted grant Ferring Pharmaceuticals

Intervention

Keyword: Follicle fluid, IVF, Metabolism, Oocyte

Outcome measures

Primary outcome

The level of lipid and carbohydrate metabolism related products in follicular

fluid

Secondary outcome

- The level of metabolism related products in serum

- IVF outcomes such as oocyte quality, fertilization, embryo development,

pregnancy and live birth and perinatal outcomes such as gestational age, birth

weight and congenital malformations.

- Nutrition of the woman in the 4 days preceding the ovum pick up

- Results of gene expression analysis of granulose cells

Study description

Background summary

Annually, 17,000 IVF treatments are performed in the Netherlands, with an average success rate of *only* 21%. Efforts are done to increase this rate in order to give more patients the possibility of raising a family. The rate of success in terms of pregnancy is determined, among other factors, by the quality of the oocytes retrieved from women by an ovarian follicle punction. One of the most important factors that affects oocyte quality, besides age, is the microenvironment of the oocyte inside the ovary, that is created by the

follicular fluid and the cumulus, granulosa and theca cells that surround the follicle. An altered follicular fluid composition alters the microenvironment of the oocyte and might play a role in deprived oocyte development and subsequent failure of the IVF treatment.
With adverse lifestyle and overnutrition as an emerging problem in our society in relation to healthy aging and fertility, the effect of lifestyle related components like lipid or carbohydrate metabolites in follicular fluid on IVF outcome parameters are of our current interest. In cows, the dietary n-6:n-3 fatty acid ratio alters the follicular fluid fatty acid profile and affects oocyte quality. Data about a direct relation between nutrition and follicular fluid composition are however limited, especially in humans, as is its relation with IVF outcome. Further, it is as yet unclear whether such diet induced changes in follicular fluid composition are related to diffusion of factors from the blood into the follicular fluid, or to altered granulosa cell metabolism and secretion into the follicular fluid.
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Study objective

Our primary objective is to assess whether maternal nutrition is reflected in serum and follicular fluid composition, and whether this affects IVF outcome. Our secondary objectives are a) to assess whether nutrition related follicular fluid composition differences are related to serum alterations and/or to an altered local metabolism in granulosa cells and b) to investigate intra-individual differences in follicular fluid composition and how these relate to IVF outcomes.

Study design

In this observational study, patients attending for a modified natural cycle (MNC) IVF treatment will be recruited for participation. The modified natural cycle IVF treatment itself will be performed as usual. Further, the women will be asked to fill in a food diary on the days between the achievement of a dominant follicle (~14mm) and the day of ovum-pick up (on average four days). At the day of ovum-pick up a blood sample of 10cc will be drawn, for which the patient has to have an empty stomach. After the ovum pick-up, when the oocyte is collected at the IVF laboratory for patient care, the follicular fluid and granulosa cells which would normally be discarded, will be stored for later analysis. The level of metabolism related components (mainly lipid and carbohydrate metabolism) will be determined in follicular fluid and the blood samples. These will be mutually compared and related to the nutrition of the woman and their IVF outcomes.

Study burden and risks

Participation does not affect the IVF-treatment of the patient in any way nor

will it benefit the patient in any way. The only discomfort consists of filling in a food diary in four days on average preceding the oocyte pick-up and in the collection of one extra tube of blood of 10 cc at the day of ovum pick-up.

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

All women attending the IVF clinic for their first course of at most six cycles of modified natural cycle with IVF or ICSI (MNC -IVF) ever or after a pregnancy

Exclusion criteria

polycystic ovary syndrome (PCOS)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2014
Enrollment:	297
Type:	Actual

Ethics review

Approved WMO Date:	20-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-06-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29551
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47569.042.13
OMON	NL-OMON29551