DONation of Oocytes in Reproduction (DONOR); clinical and immunological aspects of oocyte donation pregnancies

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Maternal complications of pregnancy
Study type	Observational non invasive

Summary

ID

NL-OMON54498

Source
ToetsingOnline

Brief title
DONOR study

Condition

- Maternal complications of pregnancy

Synonym
Preeclampsia, pregnancy toxicosis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Externe subsidie (LUF;mogelijk ZonMW)

Intervention

Keyword: Human leukocyte antigen, Oocyte donation, Preeclampsia, Reproductive immunology

Outcome measures

Primary outcome

Clinical outcome (e.g. pregnancy complications, such as miscarriage and preeclampsia) is studied in relation to the level of immunogenetic differences between mother and child.

Secondary outcome

Several aspects of the innate and cellular immune response (such as complement factors, cytokine profile and cell phenotyping) in respect to clinical outcome and pregnancy complications.

Secondary study parameters, mainly relevant for this amendment include:

- The association of a high number of fetal-maternal HLA mismatches, and the severity and time to development of pre-eclampsia in OD pregnancies.
- The association of age, parity, multiple gestation, ethnicity and other factors on the development of preeclampsia in OD pregnancies.
- The prognostic effect of other factors (such as age, indication of OD, etc.), including level of HLA mismatches, on the development of preeclampsia in OD pregnancies.
- To develop a prediction model to predict development of hypertensive disease during OD pregnancy.

Study description

Background summary

Oocyte donation (OD) is a specific method of assisted reproductive technology that enables women with various causes of reproductive failure to conceive, but is accompanied with a high risk for certain pregnancy disorders. Compared to spontaneous and in vitro fertilization (IVF) pregnancies, OD pregnancies are associated with a 30-50% higher risk for hypertensive complications. Possibly, the immunogenetic differences between mother and fetus, expressed in HLA mismatches, may play a role in the development of these complications.

Study objective

The aim of the DONOR study is to define if OD pregnancies, specifically those with immunogenetic differences between mother and child, are associated with abnormal placentation and vasculogenesis, resulting in distinct maternal immunomodulation and specific pregnancy complications. With this amendment, we seek permission to include retro- and prospective cohorts from UMCG, Isala, and Nijgeertgen to increase inclusivity and population diversity, aiming to develop the first predictive model for hypertensive complications in egg donation pregnancies (secondary outcome measure). The estimated study end date remains 01-01-2026.

Study design

The project will be performed as a multicentre prospective and retrospective cohort study.

Study burden and risks

No experimental medication will be used. Women will be treated according to local hospital protocol. For the withdrawal of blood, hardly any serious adverse events are to be expected. For the prospective cohort study, no additional hospital visits are required. For the retrospective cohort study, an additional hospital visit or at home visit will be necessary if women are wanting to participate in the collection of their blood and saliva of their child(ren). The web-based questionnaire is estimated to be a little burden, as some questions may be confrontational.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Women who conceived through IVF/ICSI with donated oocytes or autologous oocytes, women who conceived after embryo donation, women with surrogacy pregnancy, and women with spontaneously conceived pregnancies.

Exclusion criteria

Subjects that are mentally or legally incapable or with known chromosomal abnormalities (e.g. Turner XO syndrome) will be excluded.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	541
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	24-08-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	19-04-2022
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	18-10-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	02-05-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL56308.058.16