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The association of genetic variants and outcome of in vitro fertilization cycles

Submission date
22/12/2015

Recruitment status
No longer recruiting

Registration date
07/01/2016

Overall study status
Completed

Last Edited
05/02/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In vitro fertilisation (IVF) is a technique used to help people with fertility problems to have a baby. During IVF, the egg is fertilised by the sperm outside of the body to create an embryo and then returned to the woman's uterus to develop. Although IVF has become more and more successful in recent years, there is still a relatively high failure rate. The exact reasons for this are not known, however recent studies suggest that levels of different hormones in the body could play a role. The production of different hormones is determined by genes, which can vary greatly from person to person. The aim of this study is to find out whether there is a relationship between the different variants of hormonal genes and the success of IVF treatment.

Who can participate?
Women aged 20 to 45 years who are suitable for IVF treatment.

What does the study involve?
All of the participants undergo standard IVF treatment and donate 10 ml of blood for the genetic variants tests.

What are the possible benefits and risks of participating?
There are no additional benefits or risks for those taking part in the study as the treatment process is the same for those who are and are not taking part in the study.

Where is the study run from?
Lee Women's Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
December 2013 to December 2016

Who is funding the study?
United Arab Emirates University (United Arab Emirates)

Who is the main contact?
Dr Tsung-Hsien Lee
jackth.lee@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Tsung-Hsien Lee

Contact details
Chung Shan Medical Unviersity Hospital
No.110 Sec.1
Jianguo N.Rd.
Taichung
Taiwan
402
+886 (0)4 24739595 (ext 20723)
jackth.lee@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The research of gene polymorphisms of hormonal signals genes in women entering in vitro fertilization program

Study objectives
The outcome of in vitro fertilization (IVF) cycles is associated with hormonal genetic variants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Chung Shan Medical University Hospital, 12/11/2013, ref: CS13194

Study design

Single-centre observational prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
In vitro fertilization (IVF)

Interventions
All participating patients received controlled ovarian hyperstimulation protocols and oocyte retrieval procedures to get a number of oocytes. These oocytes were processed with in vitro fertilization/intracytoplasmic sperm injection to get embryos. Then we transferred the embryos back into the uterus. The duration of observation is at least one month. If a patient became pregnant, we followed her up for about one year until the delivery of baby.

Intervention Type
Mixed

Primary outcome measure
Oocyte number, measured using microscopy observation at the time of oocyte retrieval

Secondary outcome measures
1. Embryo quality is measured using microscopy observation for the number of blastomere, fragmentation degree at day 3 or day 5 after oocyte retrieval
2. Pregnancy rate is measured using serum beta-HCG test and ultrasound examination at 18 days and 32 days after oocyte retrieval, respectively
3. Implantation rate is measured using the total sac numbers divided by total transfer embryo number at the time of ultrasound examination

Overall study start date
16/12/2013

Completion date
15/12/2016

Eligibility

Key inclusion criteria
1. Age 20 to 45 years old
2. Infertile patients who need IVF treatment
3. Qualified for IVF treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
2000

Total final enrolment
1744

Key exclusion criteria
1. Part of the oocyte donation program
2. Part of the sperm donation program

Date of first enrolment
23/12/2013

Date of final enrolment
15/12/2015

Locations

Countries of recruitment
Taiwan

Study participating centre
Lee Women's Hospital
263 Pei-Tun Road
Pei-Tun Strict
Tiachung
Taiwan
402

Sponsor information

Organisation
Chung Shan Medical Unviersity Hospital

Sponsor details
No.110 Sec.1
Jianguo N.Rd.
Taichung
Taiwan
402

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/059ryjv25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chung Shan Medical University Hospital

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Taiwan

Results and Publications

Publication and dissemination plan
Planned publication of several papers about the ovarian response, pregnancy, and implantation process in peer-reviewed journals.

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		19/02/2019		No	No
Results article		08/03/2019	15/02/2023	Yes	No
Results article		30/06/2021	15/02/2023	Yes	No
Results article		19/01/2023	05/02/2025	Yes	No