

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

Submission date 22/12/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/01/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/02/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

Dr Tsung-Hsien Lee

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

20 years

Upper age limit

45 years

Sex

Female

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

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Sponsor information

Organisation

Chung Shan Medical University Hospital

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

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?
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
Basic results		19/02/2019		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes