

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

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

## 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

402

## **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?
<a href="#">Results article</a>		08/03/2019	15/02/2023	Yes	No
<a href="#">Results article</a>		30/06/2021	15/02/2023	Yes	No
<a href="#">Results article</a>		19/01/2023	05/02/2025	Yes	No
<a href="#">Basic results</a>		19/02/2019		No	No