

The effectiveness of preventing premature luteinizing hormone surge by cetorelix in the controlled ovarian stimulation by letrozole and gonadotropin

Submission date 02/07/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/07/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/01/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The effectiveness of preventing premature luteinizing hormone surge by cetrorelix in the controlled ovarian stimulation by letrozole and gonadotropin

Acronym

GnRH antagonist

Study objectives

Inhibition of premature luteinizing hormone (LH) surge by cetrorelix in letrozole/follicle-stimulating hormone (FSH) may benefit pregnancy rate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Institutional Review Board of Shin Kong Wu Wo-Su Memorial Hospital on 22/08 /2004; reference number: 94E-168

Study design

Randomized clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Couples with unexplained or mild male factor infertility

Interventions

Letrozole/FSH/cetrorelix versus Letrozole/FSH

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Letrozole, cetrorelix

Primary outcome measure

Premature LH surge rate

Secondary outcome measures

1. Pregnancy rate
2. Serum levels of inhibin B and leptin

Overall study start date

01/01/2005

Completion date

31/08/2006

Eligibility**Key inclusion criteria**

1. Patients of unexplained or mild male factor infertility
2. Body mass index (BMI) of 18-29 kg/m²

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

60

Total final enrolment

61

Key exclusion criteria

1. Anovulatory patients
2. Age ≥ 38 years of age
3. Day 3 FSH ≥ 10 mIU/ml
4. Previous low ovarian response by other controlled ovarian hyperstimulation (COH) protocol e.g. clomiphene citrate (CC)/FSH or FSH

Date of first enrolment

01/01/2005

Date of final enrolment

31/08/2006

Locations

Countries of recruitment

Taiwan

Study participating centre

95 Wen-Chaung Road

Taipei

Taiwan

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Sponsor information

Organisation

Shin Kong Hospital Research Department (Taiwan)

Sponsor details

95 Wen-Chaung Road

Taipei

Taiwan

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04x744g62>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Shin Kong Wu Ho-Su Memorial Hospital Research Department

Funder Name

(SKH-8302-95-DR-21)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2008	08/01/2021	Yes	No