ISRCTN75248474 https://doi.org/10.1186/ISRCTN75248474

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

Submission date	Recruitment status	[_] Prospectively registered
02/07/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/01/2021	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 infetility

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/m^2

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
111

Sponsor information

Organisation
Shin Kong Hospital Research Department (Taiwan)

Sponsor details
95 Wen-Chaung Road
Taipei
Taiwan
111

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