

GnRH antagonist administration for patients at high risk of severe Ovarian Hyperstimulation Syndrome (OHSS) down regulated GnRH agonist

Submission date 14/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/08/2009	Condition category Urological and Genital Diseases	<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

Study objectives

Gonadotropin-Releasing Hormone (GnRH) antagonist has a direct impact on granulosa cells reducing estradiol (E2) production, thus may reduce incidence of severe OHSS

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Institutional review board, August 2005

Study design

Prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Ovarian Hyperstimulation Syndrome (OHSS)

Interventions

GnRH antagonist versus coasting (care as usual)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

GnRH antagonist

Primary outcome measure

Current information as of 24/08/09:

High quality embryos

Initial information at time of registration:

OHSS

Secondary outcome measures

Current information as of 24/08/09:

1. Days of intervention
2. Number of oocytes
3. Pregnancy rate
4. Number of cryopreserved embryos
5. Incidence of severe OHSS

Initial information at time of registration:

Pregnancy rate

Overall study start date

30/11/2005

Completion date

01/06/2006

Eligibility

Key inclusion criteria

Women undergoing in vitro fertilisation (IVF) or IntraCytoplasmic Sperm Injection (ICSI) trial down regulated with GnRH agonist and at risk of severe OHSS

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

216 (108 - antagonist; 108 - coasting)

Key exclusion criteria

1. Women above 39 years old
2. Medical illness

Date of first enrolment

30/11/2005

Date of final enrolment

01/06/2006

Locations

Countries of recruitment

Egypt

Study participating centre

3, Street 161

Cairo

Egypt

11431

Sponsor information

Organisation

The Egyptian IVF-ET Centre (Egypt)

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/035aahr55>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The Egyptian IVF-ET center

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	01/09/2007		Yes	No