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

Submission date	Recruitment status	[_] Prospectively registered
14/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/08/2009	Urological and Genital Diseases	

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

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