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# Can a dopamine agonist prevent severe ovarian hyperstimulation syndrome (OHSS) in women undergoing intracytoplasmic sperm injection (ICSI) treatment cycles?

**Submission date**
21/05/2011

**Recruitment status**
No longer recruiting

**Registration date**
19/07/2011

**Overall study status**
Completed

**Last Edited**
30/06/2017

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Ovarian hyperstimulation syndrome (OHSS) is a complication that can affect women taking injectable hormone medications to stimulate the development of eggs in the ovaries (controlled ovarian hyperstimulation). This can occur in women undergoing in vitro fertilization (IVF), which is a process by which egg cells are fertilized by sperm outside the body. Most cases of OHSS are mild, but a small proportion is severe. The symptoms include swollen and painful ovaries, rapid weight gain, abdominal pain, vomiting and shortness of breath. The aim of this study is to find out whether the drug cabergoline can prevent severe OHSS in women undergoing IVF who are at a high risk of developing OHSS.

Who can participate?
Women undergoing IVF who are at a high risk of developing OHSS

What does the study involve?
Participants undergo controlled ovarian hyperstimulation and are randomly allocated to be treated with cabergoline or not. The eggs are retrieved 34 - 36 hours later. The eggs are fertilized and the resulting embryos are transferred into the womb 72 hours later. The incidence, onset and severity of OHSS are compared between the two groups.

What are the possible benefits and risks of participating?
Patients who take part in this study visit the hospital more frequently and therefore are monitored more closely. Side effects from cabergoline are extremely rare. It has been reported that cabergoline is linked with the development of cardiac valvuopathy (abnormal thickening and stiffness of the heart valves).

Where is the study run from?
Dr Samir Abbas Medical Center (Saudi Arabia)

When is the study starting and how long is it expected to run for?
July 2007 to June 2009

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Amany Shaltout
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Amany Shaltout

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# Additional identifiers

### Protocol serial number
SAC 05-12011

# Study information

### Scientific Title
Cabergoline and OHSS - a randomized controlled study

### Acronym
COHSS

### Study objectives
Capillary permeability is the end step of the cascade of the pathophysiology of OHSS which is associated with third space fluid accumulation and fluid shift. Vascular endothelial growth factor (VEGF) is one of the vasoactive mediators which increases capillary permeability and expressed at a higher level in the granulose cells. The administration of a dopamine agonist in immature rats at low doses simultaneously with human chorionic gonadotropin (HCG) prevented an increase in vascular permeability and did not affect angiogenesis; the effect was due to the availability of dopamine type 2 receptors. Dopamine agonists prevent the phosphorylation of

VEGF receptor 2 and reduce the in vitro and in vivo release of vasoactive angiogenic agents. As a result, vascular permeability is also reduce. Consequently, dopamine agonist has been supposed to be a potential new strategy to prevent OHSS and reduce the severity.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Samir Abbas Ethics Board, December 2006

## Study design
Single-center non-blinded randomized controlled study

## Primary study design
Interventional

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Ovarian hyperstimulation syndrome (OHSS)

## Interventions
1. Long mid luteal GnRH agonist protocol, 0.1 mg triptorelin SC. (Decapeptyl; Ferring; Germany) has been used for pituitary down regulation in both groups
2. Once pituitary down regulation has been confirmed, controlled ovarian hyperstimulation (COH) was started using fixed dose of HMG, 150- 225 IU (Menogon 75 IU,IM injections, Ferring, Germany), for 5 days, then the dose was adjusted according to response
3. When 3 leading follicles reached 18 mm, final oocyte maturation was triggered with a single dose of 5000 IU of hCG
4. On day of hCG administration, couples were randomized using computer generated list with closed opaque envelops into two groups, cabergoline group (Group I; n=100), received 0.25 mg daily for 8 days and non-cabergolone group (Group II; n=100), did not receive cabergoline
5. Transvaginal guided oocyte retrieval was performed 34 - 36 hours later
6. Both groups have been administrated 500 ml of hydroxyethyl starch (HES) over 30 minutes as a routine strategy in our center on the day of ovum pickup
7. Ultrasound guided transfer (ET) of 2-3 embryos was performed 72 hours later
8. Luteal phase was supported with 400 mg progesterone vaginal pessaries, twice daily up to the day of pregnancy test (Cyclogest; Cox Pharmaceuticals, Whiddon Valley, UK)
9. Haemoconcentration, presence of ascitis, measuring the perpendicular diameter of free fluid in Douglas Pouch, and the ovarian volume have been reported in both groups on day of ET

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Cabergoline

### Primary outcome(s)
Incidence, onset and severity of OHSS

### Key secondary outcome(s))
1. Oocyte recovery rate
2. Number of mature oocytes
3. Fertilization rate
4. Clinical pregnancy rate (defined as presence of fetal heart pulsation 2 weeks after a positive β-HCG test)

### Completion date
01/06/2009

## Eligibility

### Key inclusion criteria
1. 200 infertile couples undergoing ICSI and at risk of developing OHSS have been included between January 2007 and July 2009
2. The risk to develop OHSS has been defined as follows:
2.1. Dopamine E2 level on day of hCG > 3500 pg/ml
2.2. With ≥ 20 follicles > 12 mm

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
Patients with dopamine E2 ≥5000 pg/ml

### Date of first enrolment
01/07/2007

### Date of final enrolment
01/06/2009

## Locations

### Countries of recruitment
Saudi Arabia

**Study participating centre**
**Dr Samir Abbas Medical Center**
Jeddah
Saudi Arabia
21473

# Sponsor information

**Organisation**
Samir Abbas Center (Saudi Arabia)

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

## 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 | 01/09/2010 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |