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Urinary follicle stimulating hormone (FSH) usage in in vitro fertilisation (IVF) cycles

Submission date	Recruitment status	[X] Prospectively registered
22/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/06/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/02/2019	Pregnancy and Childbirth	[ ] Record updated in last year

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
NCT00677573

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of efficiency of recombinant follicle stimulating hormone (rec-FSH) and highly purified urinary follicle stimulating hormone (FSH) among women undergoing assisted reproductive treatment (ART)

Study objectives
One of the most accepted patient friendly ovulation induction method for patients undergoing IVF seems to be protocols with gonadotropin-releasing hormone (GnRH) antagonist. Conceivably benefits of luteinising hormone (LH) activity and low cost may favor urinary gonadotropins.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the German Hospital in Istanbul on the 2nd May 2008 (ref: 17).

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Primary infertility

Interventions
Group A: starts with recombinant FSH (r-FSH)
Group B: starts with only urinary FSH (u-FSH)

In both groups GnRH antagonist will be initiated when leading follicle is 13 mm or on day 6 of stimulation.

Interventions:
Serum assays of baseline FSH, LH, oestrogen (E2), progesterone, testesterone on day 2 of cycle

and serum assays of LH, E2, testosterone and progesterone on human chorionic gonadotropin (HCG) day and ovum pick-up (OPU) day.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Number of oocytes retrieved, 12 days following embryo transfer.

Secondary outcome measures
1. Pregnancy rate
2. Implantation rate
3. Duration of stimulation
4. Gonadotropin consumption

All secondary outcomes measured at 12 days following embryo transfer.

Overall study start date
25/06/2008

Completion date
30/11/2008

Eligibility

Key inclusion criteria
1. Women less than 42 years old
2. Healthy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Any of the ovary removed surgically
2. Surgically retrieved spermatozoa
3. FSH level over 13 mIU/ml

Date of first enrolment

25/06/2008

Date of final enrolment
30/11/2008

Locations

Countries of recruitment
Türkiye

Study participating centre
Alman Hastanesi
Istanbul
Türkiye
80200

Sponsor information

Organisation
Bahceci Women Health Care Center (Turkey)

Sponsor details
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bahceci Women Health Care Center (Turkey)

Funder Name
German Hospital in Istanbul (Turkey)

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