PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Prospective, Open Label, Randomised, Parallel Group, Comparative Pilot Study to Study the Efficacy and Safety of Highly Purified Menotrophin Versus Recombinant FSH (Follitropin Alfa) Administered Subcutaneously to Subfertile Female Patients Undergoing IVF Using Antagonist Downregulation

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Prospective open label, randomised, parallel group, comparative pilot.

Brief Summary in Scientific Language

Ongoing pregnancy rate, defined as positive fetal heart action 9 weeks after the first positive pregnancy test. Number/diameter of follicles, number of oocytes retrieved, number of pronuclear oocytes (referred to as zygotes or pre-embryos in the UK), quality of pronuclear stage oocytes, number of embryos transferred, quality of embryos, number of frozen embryos, endometrial thickness and morphology on day of HCG administration, estradiol levels at day of HCG administration, implantation rate, number of days stimulated with gonadotrophins and number of ampoules used, clinical pregnancy rate at 6 weeks after the first positive pregnancy test, pregnancy outcome.

Organizational Data

- DRKS-ID: **DRKS00004075**
- Date of Registration in DRKS: **2012/11/09**
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Date of Registration in DRKS: **2012/11/09**
Date of Registration in Partner Registry or other Primary Registry: **2005/11/22**

- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2004-001307-35**
- Primary Registry-ID: **NCT00257556 (ClinicalTrials.gov)**
- Sponsor-ID: **FE999906 CS004 (PROSPECT) (Ferring Pharmaceuticals)**
- Other Secondary-ID: **2004-001307-35**

Health condition or Problem studied

- Free text: **Infertility**
- ICD10: **N97 - Female infertility**

Interventions/Observational Groups

- Arm 1: **Drug: Menotrophin**
- Arm 2: **Drug: Follitropin alfa**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
-

Study Type: **Interventional**

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Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **IV**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Number of Participants With an Ongoing Pregnancy; time frame: Approx week 13; 9 weeks or more after the 1st positive pregnancy test
- Percentage of Participants With an Ongoing Pregnancy; time frame: Approx week 13; 9 weeks or more after the first positive pregnancy test

Secondary Outcome

- Participants With Varying Numbers of Follicles That Were Greater Than or Equal to 17 Millimeters; time frame: Day 7 and, if appropriate, every 2 days thereafter (Days 9/11/13)
- Participants With Varying Numbers of Oocytes Retrieved; time frame: Approximately study day 15
- Participants With Varying Numbers of Pronuclear Stage Oocytes; time frame: Approximately study day 15
- Participants With Varying Numbers of Embryos Transferred; time frame: Approximately study day 17
- Participants With Varying Numbers of Embryos Frozen; time frame: Approximately study day 17
- Mean Number of Days Stimulated With Gonadotrophins; time frame: study days 1 - 13
- Pregnancy Outcomes; time frame: Approximately 10 months
- Mean Endometrial Thickness; time frame: Day 7 or 9 or 11 or 13
- Mean Estradiol Level; time frame: Day 7 or 9 or 11 or 13

Countries of recruitment

- DE **Germany**
- UK **United Kingdom**

Locations of Recruitment

- **Gemeinschaftspraxis und Tagesklinik, Olpe 19, Dortmund**
- **Universitats-Frauenklinik Heidelberg Abt. Gynakologische Endokrinologie und Fertilitatsstorungen, Voßstr. 9, Heidelberg**
- **Gemeinschaftspraxis und Tagesklinik, Zingel 29, Hildesheim**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2005/10/31**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **20 Years**
- Maximum Age: **35 Years**

Additional Inclusion Criteria

**Female patients aged > or = 20 and < or = 35 years with a BMI of >18 and <32 kg/m2 who
have received no more than two previous cycles of in vitro fertilisation (IVF) or other
assisted reproductive technique (ART) and whose partners have normal sperm (according to
WHO 1999 criteria).**

Inclusion criteria:

- Signed informed consent;

- Subfertile premenopausal female patients eligible for IVF treatment;

- Aged >=20 and <=35 years;

- Body mass index of >18 and <32 kg/m2

- Normal endocrine assessment within the last 6 months;

**- Normal pelvic ultrasound (showing two ovaries, no ovarian abnormalities and normal
uterus) within the last 6 months;**

- Receipt of no more than two previous cycles of IVF (or other ART);

- At least 3 consecutive ovulatory menstrual cycles of 24-35 days, and documented evidence of ovulatory cycles within the previous 12 months;

- No fertility-modifying treatment within the 3 months prior to this treatment cycle;

- Infertility attributable to or in association with either tubal factor, or unexplained causes;

- Sperm of partner classed as normal according to WHO 1999 criteria within the year prior to beginning therapy;

- Negative serum beta-HCG pregnancy test prior to beginning therapy;

- Clinically normal baseline haematology, clinical chemistry, and urinalysis parameter values, negative serum HBsAg and HIV antibody tests;

- Screening endocrine test results (estradiol, LH, FSH, progesterone, prolactin, TSH) in early follicular phase within the normal limits for the clinical laboratory.

Exclusion criteria

Exclusion criteria

- Presence of any clinically relevant systemic disease(e.g. insulin-dependent diabetes mellitus);

- A history of or current endocrine disease, including polycystic ovary- like syndrome and hyperprolactinaemia;

- A history of coagulation disorders;

- Persistent ovarian cysts;

- Contraindications for the use of gonadotrophins or GnRH antagonists;

- A history of hypersensitivity to any of the constituents of the study medication or related compounds;

- Three or more previous cycles of IVF (or other ART);

- A history of alcohol abuse (more than 30 units per week on a regular basis);

- History of chemo- or radiotherapy;

- Currently breast-feeding, pregnant or with a contraindication to pregnancy;

- Diagnosed poor responders in prior IVF treatment;

- History of severe ovarian hyperstimulation syndrome (OHSS) (4 or 5) in former IVF treatment;

- Investigational drug within the 30 days prior to treatment;

- Any other condition or history that the investigator considers might increase the risk to the individual.

Addresses

■ **Primary Sponsor**

Ferring Pharmaceuticals

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Ferring Pharmaceuticals
Clinical Development Support

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Public Queries**

Ferring Pharmaceuticals
Clinical Development Support

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

■ **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

[---]*

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Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2009/04/01**

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 5
- Last processed date by ClinicalTrials.gov: 2016/01/14
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.