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

Trial Description

Title

A Phase III Assessor-blinded Randomized Parallel Group Multi-centre Study to Compare Efficacy and Safety of Two r-hFSH Formulations (AFOLIA Versus Gonal-f) in Women for Assisted Reproductive Treatment

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**Ther purpose of this study is to show equivalence with regard to the number of oocytes
retrieved between AFOLIA and Gonal-f® in women for assisted reproductive treatment**

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00004132**
- Date of Registration in DRKS: **2012/10/16**
- Date of Registration in Partner Registry or other Primary Registry: **2010/05/10**
- 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): **2010-019287-37**
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Primary Registry-ID: **NCT01121666 (ClinicalTrials.gov)**

- Sponsor-ID: **FIN3001 (Finox AG)**
- Other Secondary-ID: **2010-019287-37**

Health condition or Problem studied

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

Interventions/Observational Groups

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

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Number of oocytes retrieved; time frame: At the day of hCG administration but not longer than 16 days after start of treatment with r-hFSH

Secondary Outcome

- Number and size of follicles ≥ 12 mm at day 8 of stimulation and number and size of follicles ≥ 12 mm at the day of hCG administration; time frame: Day 8 of stimulation and at the day of hCG administration but not longer than 16 days
- E2 concentration at day 8 and at day of hCG administration; time frame: Day 8 of stimulation and at the day of hCG administration but not longer than 16 days
- Trough level of FSH after repeated administration of r-hFSH; time frame: Day 8 of stimulation and at the day of hCG administration but not longer than 16 days

- Quality of oocytes retrieved; time frame: At the day of oocyte retrieval
- Fertilisation rate of oocytes; time frame: At the day of oocyte retrieval
- Embryo quality; time frame: At the day of embryo transfer
- Number of cryopreserved embryos/blastocysts; time frame: At the day of embryo transfer
- Total dose of r-hFSH required; time frame: At the day of hCG administration
- Number of days of r-hFSH stimulation; time frame: At the day of hCG administration
- Number of patients with cycle cancellation; time frame: At the end of the study
- Number of non-responders; time frame: At the end of the study
- Local and systemic adverse events; time frame: During the study
- Implantation rate; time frame: Two weeks after oocyte retrieval
- Clinical pregnancy rate; time frame: Five to six weeks after oocyte retrieval
- Ongoing pregnancy; time frame: After childbirth with questionnaire
- Live birth rate; time frame: After childbirth with questionnaire

Countries of recruitment

- AT **Austria**
- DK **Denmark**
- DE **Germany**
- ES **Spain**
- CH **Switzerland**
- UK **United Kingdom**

Locations of Recruitment

- **Universitätsklinikum Bonn, Bonn**
- **Universitäts-Frauenklinik, Heidelberg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/06/30**
- Target Sample Size: **393**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

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Minimum Age: **20 Years**

■ Maximum Age: **38 Years**

Additional Inclusion Criteria

- Age between 20 and 38 years with regular menstrual cycles of 25-35 days

- First or second cycle in the present series of ART

- BMI ≥ 18 ≤ 30 kg/m2

- Basal FSH < 10 IU/L (cycle day 2-5)

- E2 levels < 50pg/mL (< 0.18 nmol/L) at the day of FSH administration

- Antral follicle count (AFC) ≥ 10 to ≤ 25 follicles (sum of both ovaries)

- Infertility due to any of the following factors: tubal factor, mild endometriosis (ASRM stage 1-2), male factor, unexplained infertility

- Presence of both ovaries and normal uterine cavity (confirmed by transvaginal ultrasound within 6 months before randomisation)

- Willingness to participate in the study and to comply with the study protocol

- Informed consent

Exclusion criteria

- Presence of pregnancy

- History of ≥2 succeeding ART cycles (IVF and/or ICSI) before the study cycle without clinical pregnancy

- Presence of clinically significant systemic disease

- Presence of chronic cardiovascular, hepatic, renal or pulmonary disease

- Presence of uncontrolled endocrine disorder

- Previous history or presence of severe ovarian hyperstimulation syndrome

- Presence of polycystic ovaries (PCO)

- Presence of severe endometriosis (ASRM stage 3 or stage 4) and hydrosalpinx

- Neoplasia

- Abnormal bleeding of undetermined origin

- History of poor response to gonadotropin treatment (defined as fewer than 5 oocytes retrieved in a previous attempt)

- Male infertility without mobile spermatozoa in the ejaculate, that need testicular of epididymal sperm retrieval (MESA/TESE/TESA)

- Endocrine abnormality such as TSH or prolactin level elevations outside the reference range if clinically relevant at screening

- Any hormonal treatment within 1 month before the start of the FSH treatment (with the exception of levothyroxin)

- History of drug, nicotine or alcohol abuse within the last 12 months (> 10 cigarettes/day)

- Administration of other investigational products within the last month

- Clinically abnormal findings at Visit 1

- Planned PGS/PGD/PBB or assisted hatching

- Concomitant participation in an other study protocol

Addresses

■ **Primary Sponsor**

Finox AG

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

■ **Contact for Scientific Queries**

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URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

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

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/03/01**

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.