Fiona-1 Study

A clinical study to evaluate safety and performance of Fiona Levonorgestrel – Releasing Intrauterine System

Study Design

- An open label, post-marketing clinical study
- 309 subjects at 21 sites across India

Reference No.	**CTRI/2016/03/006781**
Study Objective	**1. The primary objective was to evaluate safety and performance of Fiona Levonorgestrel-Releasing Intrauterine system as indicated by:** **a. No clinical features of intolerance or complications developing within 2 months of study system insertion** **b. Non-failure of contraception in presence of Fiona Levonorgestrel-Releasing Intrauterine system** **c. No chronic complication up to 5 years** **d. No auto-expulsion or dislocation of the study device** **2. Pharmacokinetic evaluation of plasma Levonorgestrel concentration up to 5 years**
Efficacy Endpoint	**Proportion of failure of contraception as indicated by events of pregnancies in presence of study device or due to auto-expulsion of study device** • **Number of Intra-uterine pregnancies** • **Number of ectopic pregnancies**
Safety Endpoints	**1. Proportion of population presenting intraprocedural perforation of uterus** **2. Proportion of population presenting with one or more of the following conditions within 1 month following insertion of study device** **a. Post procedural perforation of uterus** **b. Significant endometrium injury** **c. Myometrium injury** **d. Pelvic inflammatory disease, severe Leucorrhoea or endometritis not relieved by medical intervention and requires removal of study device.** **e. Expulsion or partial expulsion of the study device** **3. Proportion of subjects presenting with events of dislocation or expulsion of the study device, perforation of uterus, endometrial injury or ulcer, myometrial injury, ectopic pregnancy, salpingitis or similar conditions, suspected to be related with the study device, after one month up to 5 year from insertion of the study device**
PK Endpoint	**Demonstration of Levonorgestrel levels in blood up to 5 years.**
Clinical Sites	**21 sites across India**
Sample Size	**Total 309 subjects enrolled**

Follow-Up	**Clinical follow-up at 1 month, 3 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years**
Study Duration	**Study starts date April 2016.** **Estimated completion date August 2022.**

❖ **Reference:**

1. **Clinical Trial Registry- India (CTRI): CTRI/2016/03/006781**
   http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=14673&EncHid=&userName=CTRI/2016/03/006781