

Fiona-1 Study

Study Highlights

- Principal Investigator: Dr. Jagruti Desai
- Fiona-1 is an open-label, post-marketing, single-arm, clinical registry to evaluate safety, tolerance, and performance of Fiona™ Levonorgestrel – Releasing Intrauterine System
- Study enrolled a total of 309 subjects at 21 sites across India
- Safety, efficacy and PK endpoints will be evaluated till 5 years

❖ Study Design

An open-label, post-marketing, clinical registry



309 patients were enrolled



21 investigational sites across India



Clinical follow-up at 1 month, 3 months, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years

❖ Results at 1-year follow-up²

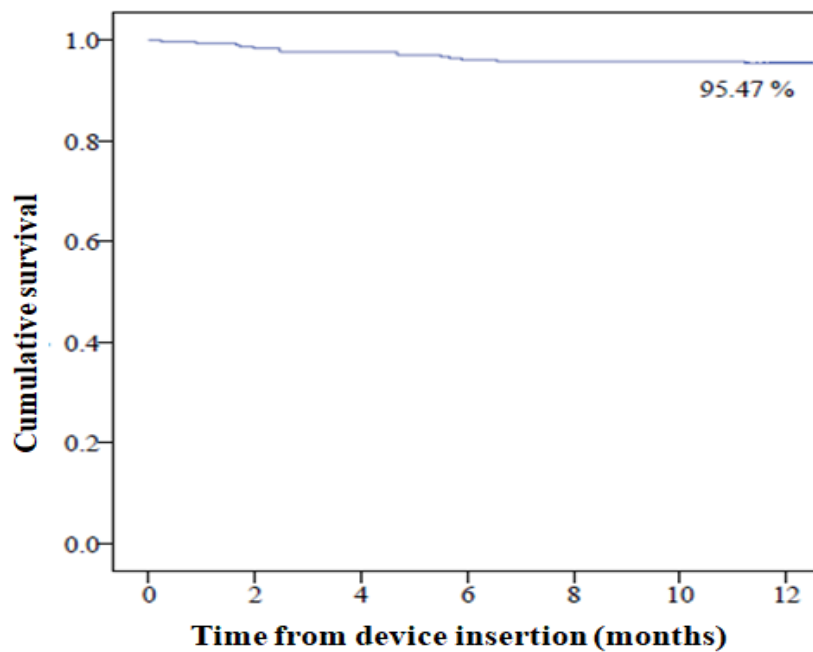


Figure 1: Kaplan–Meier survival curve of IUD continuation

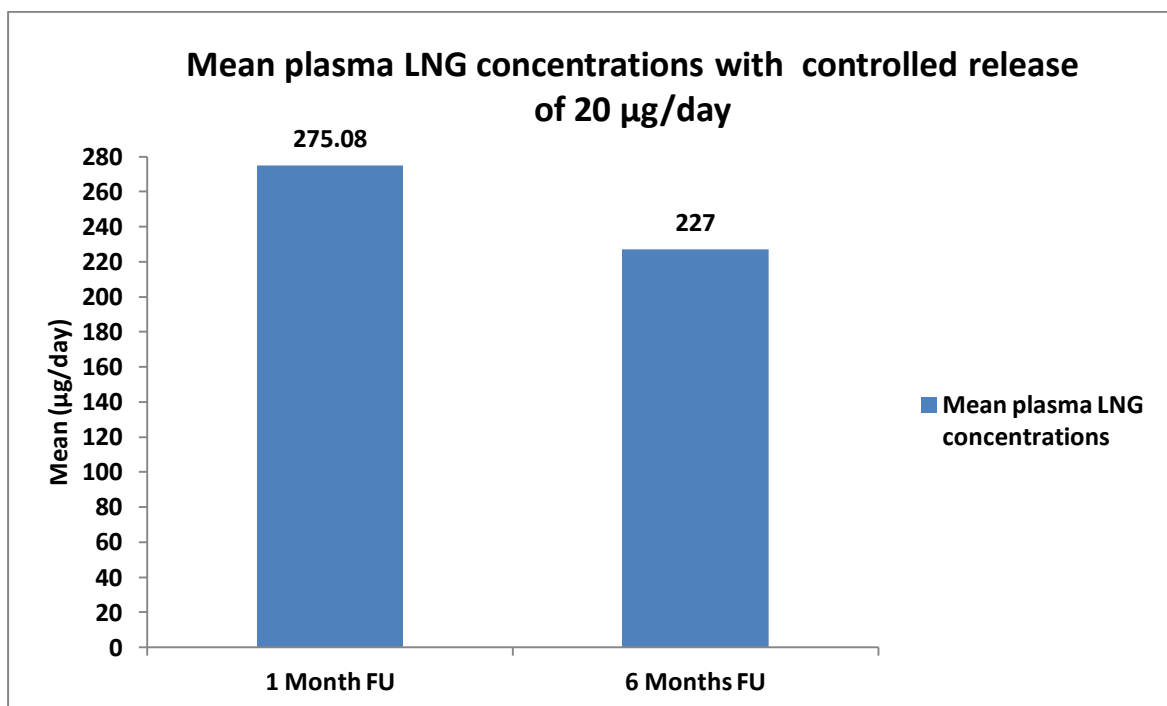


Figure 2: Mean plasma LNG concentrations at 1 and 6 months follow-up

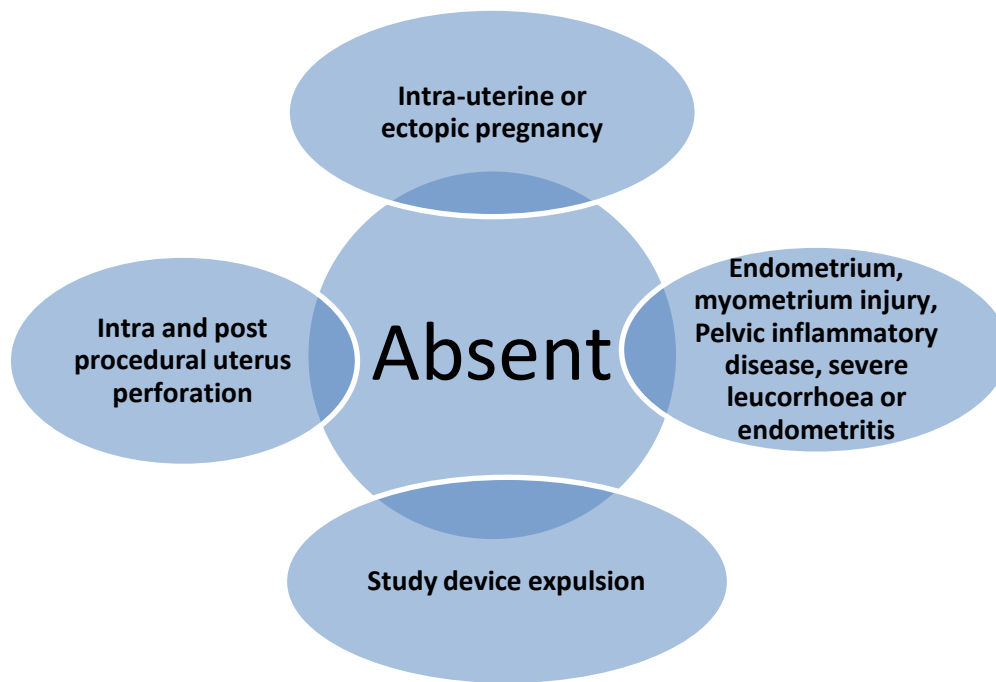


Figure 3: Safety and Efficacy outcomes

❖ **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>
2. Asha Dixit. Safety and performance of a levonorgestrel-releasing intrauterine contraceptive device: one-year outcomes of Fiona-1 clinical registry. Journal of the Indian Medical Association. 2019; 117(8):23-28.