Reading Hospital
TOWER HEALTH
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CLINICAL TRIALS OFFICE
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Full Title	POET: An open-label, non-randomized, prospective observational cohort study to assess post-procedural outcomes in two cohorts of women who chose to undergo either hysteroscopic sterilization (Essure®) or laparoscopic tubal sterilization
Principal Investigator	Stephen Fehnel, MD
Sub-Investigator	Eric Fehnel, MD Anna Grassi, DO Christopher Pugh, DO
Study Objectives	To evaluate the proportion of subjects who have undergone Essure placement compared to the proportion of subjects who had an attempt at laparoscopic tubal sterilization and experience: • new onset or worsening chronic lower abdominal and/or pelvic pain • new onset or worsening abnormal uterine bleeding • gynecologic or related surgical intervention • new onset or worsening allergic, hypersensitivity, or autoimmune-like reactions To collect data on patient reported outcomes in subjects who have undergone hysteroscopic or laparoscopic tubal sterilization procedures

Inclusion Criteria	Patients are eligible to be included in the study if they meet all of the following criteria:
	• Subject is 21 to 45 years of age
	• Subjects who are scheduled to undergo an Essure insert placement procedure for permanent birth control or laparoscopic tubal sterilization. Decision for either treatment based upon clinical practice and physician/patient counseling;
	• For the Essure group only
	  ○ Subjects selecting Essure who are willing to use alternative contraception for at least 3 months post-Essure placement procedure, until a satisfactory Essure Confirmation Test is documented;
	  ○ Subjects who are believed to have two viable fallopian tubes.

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- For the laparoscopic tubal sterilization group only:
  - Subjects selecting laparoscopic sterilization who are not contraindicated for laparoscopic tubal sterilization according to common clinical practice standard of care;
- Subjects who are willing to accept the risk of pregnancy occurring while relying on the Essure device or laparoscopic tubal sterilization for prevention of pregnancy;

Exclusion Criteria

Patients are excluded if they meet any of the following criteria:

- Subjects post-partum or undergone pregnancy termination ≤6 weeks prior to scheduled procedure;
- Subjects with an active upper or lower genital tract infection;
- Subjects with gynecologic malignancy (suspected or known);
- For the Essure group only:
  - Subjects who can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus);
  - Subjects who have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible and/or abnormal tubal anatomy or previous tubal ligation (including failed ligation);
  - Subjects who have had total or partial salpingectomies;

Affiliations & Sponsors

Bayer HealthCare

Status

Open to enrollment

Keywords

Essure, hysteroscopic sterilization, tubal sterilization, laparoscopic sterilization, sterilization, birth control