

ACOG 2022 – Mirena 8 year extension data abstract

Title

Efficacy and safety of 52mg LNG-IUS during years 6–8 of use: Data from the Mirena® Extension Trial

Authors

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Introduction:

The Mirena® Extension Trial (MET) evaluated efficacy and safety of 52mg LNG-IUS (Mirena®) during extended use.

Methods:

MET was a multicenter, single-arm US study, enrolling women aged 18–35 years who were current users of 52mg LNG-IUS for 4.5–5 years. Institutional review board approval was obtained for all centers. Contraceptive efficacy (Pearl Index, PI) of 52mg LNG-IUS beyond 5 years up to 8 years of use was assessed.

Results:

Of 362 participants starting year 6, 243 entered year 8, with 346 included in the year 8 primary analysis set (PAS, all participants aged ≤36 years at end of year 8). Mean (standard deviation) age for the year 8 PAS was 29.2 (±2.9) years and 50.9% were parous.

Two pregnancies occurred (both with device *in situ*): one of undetermined location that spontaneously resolved in year 6 and one ectopic in year 7. For years 6–8, the 3-year PI (95% confidence interval) was 0.28 (0.03–1.00), with an estimated pregnancy probability of 0.68% (0.17–2.71). PIs for years 6, 7, and 8 were 0.34 (0.01–1.88), 0.40 (0.01–2.25), and 0.00 (0.00–1.90), respectively.

Treatment-emergent adverse events were reported in 249/362 participants (68.8%) and were related to 52mg LNG-IUS in 65 (18.0%). The discontinuation rate was 38.4% (139/362), most commonly due to wish for pregnancy (12.2%, 44/362). At end of year 8, 220/223 (98.7%) were satisfied with 52mg LNG-IUS.

Conclusions/Implications:

52mg LNG-IUS, initially approved for 5 years, maintains high contraceptive efficacy, user satisfaction, and a favorable safety profile through 8 years of use.

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