ACOG 2022 – Mirena extension trial PK data abstract

Title

Estimating *in vivo* LNG release rate & exposure over 8 years LNG-IUS 52mg use with a population pharmacokinetic approach [100/100 characters]

Authors

Jeffrey T. Jensen1, Isabel Reinecke2, Eeva Lukkari-Lax3, Birte M. Hofmann4

Affiliations

1 Department of Obstetrics & Gynecology, Oregon Health & Science University, Portland, OR, USA

2 Bayer AB, Solna, Sweden

3 Bayer OY, Espoo, Finland

4 Bayer AG, Berlin, Germany

Introduction:

To characterize performance of LNG-IUS 52mg (Mirena®) over its 8-year duration of use and facilitate comparisons with LNG-IUS 19.5mg and LNG-IUS 13.5mg, we estimated in vivo LNG release rates and LNG plasma/serum concentrations using a population pharmacokinetic (popPK) approach with data from the Mirena Extension Trial (MET) and earlier clinical trials.

Methods:

Previously, we developed a popPK model based on measured plasma/serum LNG concentrations and residual LNG content from removed 52mg, 19.5mg, and 13.5mg LNG-IUS devices in clinical studies for up to 5 years of use, estimating in vivo LNG release and describing LNG exposure. To estimate release and exposure for years 6–8 of use, we applied the model to data up to 6, 7 and finally 8 years from the MET.

Results:

As expected, LNG release rates for LNG-IUS 52mg were higher than for 19.5mg and 13.5mg devices. After 8 years, LNG-IUS 52mg release rate (7.04µg/day) was similar to LNG-IUS 19.5mg after 5 years (7.6µg/day) and higher than LNG-IUS 13.5mg after 3 years (5.5µg/day).

Model-based estimated and measured LNG concentrations showed good agreement, with average plasma LNG concentrations after 8 years LNG-IUS 52mg (100ng/L [CV%:39.9%]) similar to after 5 years LNG-IUS 19.5mg (84.8ng/L [39.9%]) and higher than after 3 years LNG-IUS 13.5mg (58.1ng/L [40.8%]) use.

Conclusion/Implications:

LNG release rates from LNG-IUS 52mg at 8 years are similar to 19.5mg at 5 years, and higher than 13.5mg at 3 years. The 8-year popPK model provides in vivo LNG release rate and concentration estimates, facilitating more direct comparisons between the three LNG-IUSs.

Word count: currently 253/250 max (note: section headings do not need to be included in word count)