FSRH
Clinical Effectiveness Unit

The Faculty of Sexual & Reproductive Healthcare of the Royal College of Obstetricians & Gynaecologists

FSRH CEU Statement: Levosert® 52mg LNG-IUS: extension of licence for contraception to 6 years
8 February 2021

The Levosert® 52mg LNG-IUS has been licensed for contraceptive use for 6 years[1]. Levosert remains licensed for 5 years for management of heavy menstrual bleeding and is not licensed for endometrial protection as part of HRT.

What new evidence is available for contraceptive effectiveness in the 6th year of use?

The ongoing ACCESS IUS study in the USA[2] enrolled 1538 individuals aged 16-35 years to evaluate contraceptive effectiveness of the Levosert equivalent, Liletta® for up to 10 years of use. Data have recently been published for the 321 subjects who had continued in this study and completed 6 years of use and a further 229 subjects still in their 6th year of use at the time of reporting. It is noted that 15% of enrolled subjects were lost to follow up or withdrew consent.

No pregnancies were reported in the 6th year of use. A total of 9 pregnancies (6 of them ectopic) were recorded in years 1 to 5. The reported life table pregnancy rate for 6 years of use is 0.87% (0.44-1.70).

What did we know already?

Previous studies of extension of use of 52mg LNG-IUS devices beyond 5 years[3,4] have also reported low pregnancy rates in the 6th year of use but included significant numbers of subjects aged over 35 years at insertion, thus limiting the relevance of the findings for younger users. McNicholas *et al.* reported pregnancy rates for the 52mg LNG-IUS of 0.25 and 0.43 per 100 woman years for the 6th and 7th years of use respectively (347 subjects completed 6 years and 160 completed 7 years of use).[3] Rowe *et al.* reported a 7 year cumulative pregnancy rate for the 52mg LNG-IUS of 0.5% (681 women completed 6 years and 398 completed 7 years of use).[4]

What about other adverse events in the 6th year of use?

In the ACCESS IUS study[2], 40% of subjects (including some subjects aged between 35 and 45 years at insertion who were not part of the contraceptive effectiveness cohort described above) reported amenorrhoea for the final 90 days of the 6th year of use. This is similar to the rates of amenorrhoea reported from year 3 onward. During year 6, one user discontinued use for a “bleeding complaint”, one was diagnosed with pelvic infection and two partial expulsions were diagnosed.

How does this affect practice?

Users of the Levosert 52mg LNG-IUS can now be advised that the device can be used as highly effective contraception for 6 years. Levosert remains unlicensed for use for endometrial protection as part of HRT.

FSRH CEU will be convening an expert group to consider whether this evidence can be extrapolated to inform contraceptive effectiveness with extended use of other 52mg LNG-IUS devices.

FSRH – CEU Chalmers Centre | 2A Chalmers Street | Edinburgh | EH3 9ES | +44(0)131 536 3830
CEU.Chalmers@nhslothian.scot.nhs.uk www.fsrh.org

FSRH registered office: 10–18 Union Street | London | SE1 1SZ | Company No: 02804213 Charity No: 1019969

References

1. eMC. Summary of Product Characteristics: Levosert 20 micrograms/24 hours IDS. Last updated on emc 14/01/2021. Available online here [accessed 08/02/2021]
2. Westhoff CL, Keder LM, Gangestad A, Teal SB, Olariu AI, Creinin MD. Six-year contraceptive efficacy and continued safety of a levonorgestrel 52 mg intrauterine system. *Contraception* 2020;**101**(3):159-61.
3. McNicholas C, Maddipati R, Zhao Q, Swor E, Peipert JF. Use of the etonogestrel implant and levonorgestrel intrauterine device beyond the US Food and Drug Administration–approved duration. *Obstetrics and gynecology* 2015;**125**(3):599.
4. Rowe P, Farley T, Peregoudov A, Piaggio G, Boccard S, Landoulsi S, Meirik O. Safety and efficacy in parous women of a 52-mg levonorgestrel-medicated intrauterine device: a 7-year randomized comparative study with the TCu380A. *Contraception*. 2016;**93**(6):498-506.

The Clinical Effectiveness Unit (CEU) was formed to support the Clinical Effectiveness Committee of the Faculty of Sexual & Reproductive Healthcare (FSRH), the largest UK professional membership organisation working at the heart of sexual and reproductive healthcare. The FSRH CEU promotes evidence based clinical practice and it is fully funded by the FSRH through membership fees. It is based in Edinburgh and it provides a members' enquiry service, evidence-based guidance, new SRH product reviews and clinical audit/research. Find out more here.

FSRH – CEU Chalmers Centre | 2A Chalmers Street | Edinburgh | EH3 9ES | +44(0)131 536 3830
CEU.Chalmers@nhslothian.scot.nhs.uk www.fsrh.org

FSRH registered office: 10–18 Union Street | London | SE1 1SZ | Company No: 02804213 Charity No: 1019969