IUDs with levonorgestrel

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- LNG-IUD 19.5 (Kyleena®) is a plastic intrauterine device that releases a smaller volume of levonorgestrel than the classic LNG-IUD 52 (Mirena®). When applied for contraception, both have a lifespan of 5 years.
- The new IUD is also shorter, has a smaller width and smaller reservoir than the classic IUD, and has a narrower insertion tube. One of the arguments for introducing these changed dimensions was said to be a reduced incidence of insertion problems. However, not only has there been no research showing problems of insertion or expulsion of the LNG-IUD 52, but research into smaller IUDs has not yielded any findings showing that such smaller IUDs can be more easily inserted or that the incidence of expulsion is lower.
- No results are available of well-designed and independent randomised studies comparing the LNG-IUD 19.5 with the LNG-IUD 52 using clinically relevant outcome measures. The Phase II study discussed in the article concerns an IUD which has different dimensions, whose total amount of levonorgestrel is unclear, and for which it is unclear whether the release pattern corresponds to that of the already authorised Kyleena.
- After three years of use, there is no difference in continuation or discontinuation between low-dose and classical IUDs. There have been no randomised studies into the difference in efficacy (i.e. preventing pregnancy) between LNG-IUD 19.5 and LNG-IUD 52. The study discussed in the article, which compared the efficacy of LNG-IUD 16 with that of LNG-IUD 52, had an insufficient number of participants, which means that it could not reliably establish the efficacy. In addition, the study period, three years, was too short, as the new IUD has been authorised for five years.
- The results of the study are based on the assumption of ‘perfect use’ by women aged 21-41 years, and are probably not representative of ‘typical use’.
- It has been suggested that the risk of intrauterine bleeding problems (amenorrhoea or irregular blood loss) when using low-dose hormonal IUDs, including LNG-IUD 19.5, would be less than with traditional IUDs. No data have been published, however, about the removal rate of IUDs due to problems of intrauterine bleeding or its absence when using LNG-IUD 19.5 or the classic LNG-IUD 52.
- Assessing the efficacy for ‘typical use’ and the occurrence of low-frequency side effects requires more (observational) research among nulliparous and multiparous women, adolescents and older women.
- Research has not shown whether a low-dose IUD is better than the classic LNG-IUD 52 in terms of bleeding patterns. Without such evidence, there is no reason to start with, or switch to, the low-dose IUD, since experience with the latter is less extensive than that with the classic hormonal IUD.

Literature references

1. Productinformatie levonorgestrelspiraal (Mirena®), via: www.cbg-meb.nl, Geneesmiddeleninformatiebank.
2. Productinformatie levonorgestrelspiraal (Jaydess®), via: www.cbg-meb.nl, Geneesmiddeleninformatiebank.


*The literature refers to the Dutch text