Contraception Update 2025

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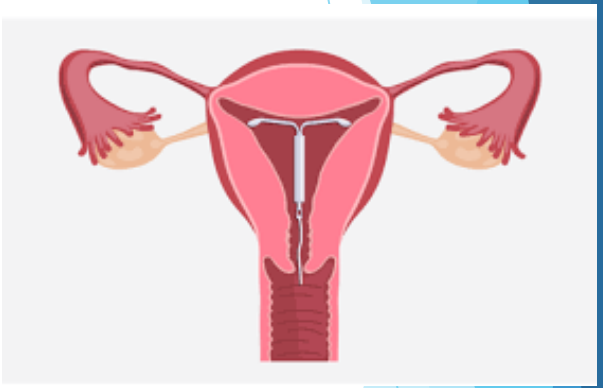
Case discussions

Case 1

- A 32-year-old female attends requesting Mirena removal and refit
- It was fitted 5 years ago for contraception and to control heavy periods
- She has been amenorrhoeic until a few months ago
- Her periods have started to return but these are not affecting her QoL
- She has no issues with this Mirena



What advice would you give to this patient?

FSRH
Clinical Effectiveness Unit

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

FSRH CEU Statement: Mirena® 52mg LNG-IUD: extension of licence for contraception to 8 years
10th January 2024

The Mirena® 52mg LNG-IUD has now been licensed for 8 years for contraception.[1]

The United Kingdom Medicines Health Regulatory Authority (MHRA) has approved an extension to the Mirena licence from 5 years to 8 years for contraception.

- Very low pregnancy rate (Pearl Index <0.4) during years 6, 7 and 8 of use
- This recommendation also applies to Mirena users who already have a device in utero.

TABLE 2
Pearl Index during extended 52-mg LNG-IUS use up to 8 years

Pearl Index	Women (n)	Relevant exposure (WY)	Pregnancies (x)	Pearl Index, per 100 WY (95% CI)
3-year (years 6, 7, 8)	346	719.20	2	0.28 (0.03–1.00)
Year 6	362	296.87	1	0.34 (0.01–1.88)
Year 7	293	247.90	1	0.40 (0.01–2.25)
Year 8	229	194.42	0	0.00 (0.00–1.90)

Intention-to-treat analysis. Our mathematical model[32] assumed that the number of pregnancies follows a Poisson-distribution. Formula: PI=x/E; lower 95 % confidence limit of PI=0.5. $\chi^2_{(0.025,\ 2x)}$ /E; upper 95 % confidence limit of PI=0.5. $\chi^2_{(0.975,\ 2(x+1))}$ /E; where x=number of pregnancies, E=exposure in 100 WY (1 WY is 365 days of relevant exposure), $\chi^2_{(alpha,\ df)}$ is the alpha quantile from χ^2-distribution with df degrees of freedom.

52-mg LNG-IUS, 52-mg levonorgestrel-releasing intrauterine system; *CI*, confidence interval; *PI*, Pearl Index; *WY*, women-years.

Jensen. Mirena Extension Trial findings in Years 6 to 8. Am J Obstet Gynecol 2022.

Mirena Ext. Trial

FSRH The Faculty of Sexual & Reproductive Healthcare

FSRH CEU Statement: Extended use of all 52mg LNG-IUDs for up to eight years for contraception

Following the change in licence of Mirena® to eight years[1], the CEU have reconvened the Intrauterine Contraception (IUC) Guideline Development Group (GDG) to consider the extended use of all 52mg LNG-IUDs to eight years for contraception. Overall, whilst the evidence is limited, the GDG felt there was sufficient evidence to make the following recommendations.

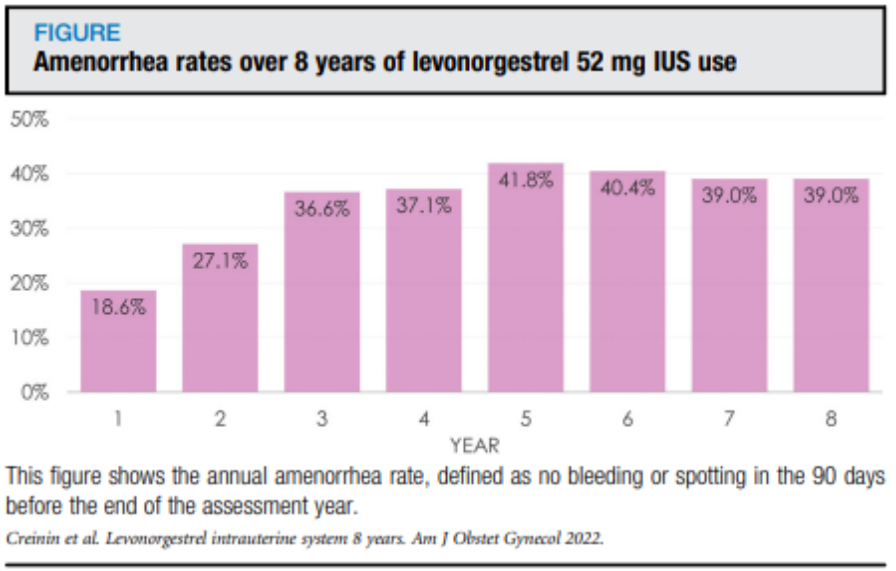
Recommendations

The FSRH IUC GDG support extended use of any 52mg LNG-IUD for up to eight years for contraception if the user is under 45 years old at the time of insertion.

There is insufficient evidence to support use of any 52mg LNG-IUD beyond eight years for contraception. If an individual presents for replacement of the device after eight years, criteria for reasonably excluding pregnancy must be met, as per FSRH guidance[2].

Mirena for Heavy Menstrual Bleeding

- The licensing remains unchanged at 5 years



ACCESS-IUS Trial

How does this affect practice?

- Users of the Mirena 52mg LNG-IUD can now be advised that the device can be used as contraception for 8 years. This also applies to individuals who already have a device in-situ.
- There are no changes to the established FSRH and British Menopause Society recommended duration of use when a Mirena 52mg LNG-IUD is being used for endometrial protection as part of HRT (5 years from time of insertion) or to existing guidance about duration of use of Mirena for heavy menstrual bleeding.

Case 1: Advice for the Patient

- **New 8-Year Licensing for Mirena:**
  - Replacement may not be needed for another 3 years if fitted for contraception
  - Not applicable for HMB
- **Returning Periods:**
  - Suggests waning hormonal effects of the Mirena
  - Current periods not impacting QoL, but replacement may prevent worsening symptoms
- **Patient's choice:**
  - Decision to replace should align with patient's preferences, based on her specific needs and circumstances

Case 2

- 38y female patient attending for smear test
- Taking Microgynon COCP
- Her current BMI is 31 and has no UKMEC contraindications for COCP use
- Recently started using weekly Mounjaro injections to reduce weight

What advice would you give this patient?

Glucagon-like peptide-1 (GLP-1 agonists)

Summary of GLP-1 agonists interactions with oral contraceptive pills (OCPs) and recommendations for patient care:

Drug	OCP Interactions and Recommendations
Tirzepatide (Mounjaro®)	Decreases bioavailability of OCPs. Recommend patient to use barrier contraception for 4 weeks after initiation or a dosage increase, or to switch to a non-oral contraceptive
Semaglutide (Ozempic®, Wegovy®)	No effect on bioavailability of OCPs.
Liraglutide (Victoza®)	No effect on bioavailability of OCPs.
Dulaglutide (Trulicity®)	No effect on bioavailability of OCPs.

GLP-1 agonists

FSRH Statement: Glucagon-like peptide-1 (GLP-1) agonists and oral contraception

Published on: 07 February 2025

The FSRH is advising that individuals use contraception whilst using GLP-1 agonists, with additional advice for those using tirzepatide. The FSRH has also produced a resource for clinicians to share with patients, which is available in the statement or via the link below.

Download FSRH statement

GLP-1 agonists and contraception patient information leaflet

Advice on contraception for individuals taking a GLP-1 agonist. These medications are commonly used for people with type 2 diabetes or to support weight loss.

Download patient information leaflet

January 2025

FSRH The Faculty of Sexual & Reproductive Healthcare

FSRH statement: Glucagon-like peptide-1 (GLP-1) agonists and oral contraception

FSRH recommendations

- **Individuals should be advised to use contraception whilst using GLP-1 agonists.**
- **Individuals using tirzepatide and oral contraception should switch to a non-oral contraceptive method, or add a barrier method of contraception, for four weeks after initiation and for four weeks after each dose increase.**
- **There is no need to add a barrier method of contraception when using semaglutide, dulaglutide, exenatide, lixisenatide or liraglutide.**
- **Individuals who experience severe diarrhoea or vomiting during use of GLP-1 agonists should follow existing FSRH recommendations.**

GLP-1 agonists and contraception

Patient information leaflet

1. What are GLP-1 agonists?

GLP-1 agonists include medications such as **tirzepatide** and **semaglutide** which may be better known by their different brand names (see below). They are prescription only medications that may be prescribed by a qualified healthcare professional for people with type two diabetes, or to facilitate weight loss. One of the main ways they work is by slowing the rate at which food leaves the stomach (delayed gastric emptying).

Medication	Brand name examples (commonly known as)
Tirzepatide	Mounjaro
Semaglutide	Ozempic, Wegovy, Rybelsus
Exenatide	Bydureon BCise
Liraglutide	Saxenda, Diavic, Victoza
Dulaglutide	Trulicity
Lixisenatide	Contained in Suliqua

2. I am taking the pill. Will using a GLP-1 agonist affect my contraception?

This depends on the type of GLP-1 agonist that you are using. If you are using tirzepatide you should use a barrier method of contraception (e.g. condoms) in addition to your pill for four weeks after starting the medication, and for four weeks after any increase in dose. This is because tirzepatide works slightly differently to the other GLP-1 agonists. Alternatively, you may wish to consider another (non-oral) method of contraception whilst using tirzepatide.

There is currently no evidence that semaglutide, exenatide, liraglutide, dulaglutide or lixisenatide reduce the effectiveness of oral contraception (i.e. the combined pill, or the progestogen only pill/ "mini-pill").

3. I have diarrhoea and vomiting with my GLP-1 agonist, and I take the contraceptive pill, what should I do?

Diarrhoea and vomiting are common side effects of the GLP-1 agonists and can reduce the effectiveness of the pill. If vomiting occurs within three hours of taking the contraceptive pill, or severe diarrhoea occurs for more than 24 hours, you should follow the guidance for missed pills. You should consider an alternative non-oral method of contraception or the addition of condoms if diarrhoea or vomiting persists.

4. What about non-oral methods of contraception e.g. the coil, implant, injection, patch or ring, could these be affected by GLP-1 agonists?

There is no reason to believe that GLP-1 agonists affect methods of contraception that are not taken by mouth, so it is okay to use any of these options. No extra precautions are needed when using these methods of contraception alongside a GLP-1 agonist.

5. I am planning to switch from one type/brand of GLP-1 to another, does the contraception advice remain the same?

If you are switching to tirzepatide from ANY other GLP-1 agonist then you should use a barrier method of contraception (such as a condom) for four weeks after the switch, and for four weeks after any increases in dose, while also continuing your oral contraception. Alternatively, you may wish to consider changing to a non-oral method of contraception whilst using tirzepatide.

6. I need emergency contraception and I'm taking a GLP-1 agonist; will it work?

We don't know yet if oral emergency contraception is affected by GLP-1 agonists. The copper IUD (coil) is the most effective method of emergency contraception and is not affected by diarrhoea and vomiting. If you require emergency contraception, please tell your healthcare practitioner about all other medications you are taking, including GLP-1 agonists.

7. Can I take a GLP-1 agonist during pregnancy?

It is important to use effective contraception whilst taking a GLP-1 agonist, as these medications should not be used in pregnancy. If you become pregnant whilst taking one of these medications it is important to discuss this with your doctor.

GLP-1 agonists should also be avoided for a number of weeks prior to a planned pregnancy. The table below shows the number of weeks recommended to have stopped the medication prior to a planned pregnancy (washout period), for some of the GLP-1 agonists.

GLP-agonist	Washout period
Tirzepatide	One month
Semaglutide	Two months
Exenatide	12 weeks

Table 1. Washout periods of GLP-1 agonists

This patient information leaflet has been written by the Faculty of Sexual and Reproductive Healthcare (FSRH). The advice given is based on FSRH recommendations, which can be found at FSRH.

Case 2

- 38y female patient attends for smear test
- Taking Microgynon COCP
- Her current BMI is 31 and has no UKMEC contraindications for COCP use
- Recently started using Mounjaro weekly injections to reduce weight

What advice would you give this patient?

Case 3

- 23y male presents with dysuria and urethral discharge
- Tests positive for Chlamydia
- PMH – Bipolar disorder
- Meds - Sodium Valproate

What advice would you give this patient regarding contraception?

GOV.UK

Home > Drug Safety Update

Valproate Pregnancy Prevention Programme: actions required now from GPs, specialists, and dispensers

Valproate medicines must not be used in women of childbearing potential unless the Pregnancy Prevention Programme is in place. If you are involved in the care of female patients on valproate in the UK, see a reminder of actions required for this medicine. You should have received a pack of information materials for patients—if you have not yet received a pack, or if you are near to running out of any materials, you should order more using the details provided in the article.

Press release

MHRA advises men taking valproate and their partners to use effective contraception

Men taking valproate and their partners are being advised by the Medicines and Healthcare products Regulatory Agency (MHRA) to use effective contraception because of new data suggesting a potential small increased risk of harm to children if valproate is used by a father at conception. Valproate is licensed for epilepsy and bipolar disorder.

From: Medicines and Healthcare products Regulatory Agency

Published 5 September 2024

FSRH The Faculty of Sexual & Reproductive Healthcare

FSRH Statement: Paternal exposure to valproate and the risk of neurodevelopmental disorders in children.

Key points

- Research has shown a possible association between valproate use by men around the time of conception and an increased risk of neurodevelopmental disorders in their children.[1]
- As a precaution, it is recommended that men and their female sexual partners use effective contraception during valproate use and for at least three months after stopping.[1]
- No one should stop taking valproate without advice from their healthcare professional.[1]

Medicines & Healthcare products Regulatory Agency

Advice for male patients on valproate to use contraception

This is for healthcare professionals to provide to male patients taking valproate as well as their families and caregivers.

Always read the information that comes with your medicine and talk to a doctor, nurse, or pharmacist if you have any concerns.

Quick advice

- Do not stop taking valproate unless your specialist advises you to because of the need to keep your condition under control.
- Use condoms while on valproate and for 3 months after stopping – ask your female sexual partner to also use birth control to prevent them from becoming pregnant
- Attend your next appointment, when invited to do so, to discuss the risks and your options
- Let your doctor know if you are planning to father a child and are on valproate.
- Do not donate sperm while on valproate or for 3 months after stopping valproate

Valproate medicines
Sodium valproate, valproic acid or valproate semisodium are valproate medicines. Valproate medicines are used in treatment of epilepsy and bipolar disorder. Brands of valproate medicines are Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell.

New information about fathering children on valproate
If you father a child while you are taking valproate, there is a potential small increased risk of the child being diagnosed with problems with their mental or movement development (neurodevelopmental disorders).

A study of health records reported that around 5 in 100 children whose fathers were taking valproate at conception had a developmental disorder. This was compared to around 3 in 100 children whose fathers were taking lamotrigine or levetiracetam; two other anti-seizure

Case 5

- A 27-year-old breastfeeding mother was given an EllaOne tablet for emergency contraception.
- She is 2 months postpartum and fully breastfeeding.

- What advice would you give her regarding breastfeeding?

FSRH The Faculty of Sexual & Reproductive Healthcare

FSRH Guideline

Emergency Contraception

12.2 UPA-EC

D	**Breastfeeding women should be advised not to breastfeed and to express and discard milk for a week after they have taken UPA-EC.**

UPA is excreted in breast milk. The safety of use of UPA-EC during breastfeeding has not been studied. The SPC for ellaOne advises that breastfeeding is avoided for a week after using UPA-EC; milk should be expressed and discarded during that time.[58]

Evidence level 4

FSRH The Faculty of Sexual & Reproductive Healthcare

FSRH Statement: Ulipristal Acetate and Breastfeeding

January 2025

Recommendation

No interruption of breastfeeding is necessary following a single dose of Ulipristal Acetate when given for Emergency Contraception.

Following a review of the current recommendation, which states that breast milk should be expressed and discarded for one week after Ulipristal Acetate (UPA) (1), members of the Guideline Development Group (GDG) for the FSRH Guideline Emergency Contraception (EC) have agreed a recommendation that there is no need to avoid breastfeeding after taking a single dose of UPA-EC. This is in line with recommendations from the UK Drugs in Lactation Advisory Service (UKDILAS), which are published on the Specialist Pharmacy Service website (2).

The evidence

The published evidence is limited to one pharmacokinetic study (3). There is no published evidence relating to the effect of UPA-EC on the infants of breastfeeding women, including no published evidence of any harm.

The breast milk of 12 lactating women was collected in 24-hour increments after administration of UPA (dose not specified, but presumably 30mg). Concentrations of UPA in breast milk were measured and amounts were found to be negligible (table 1).

Hours since administration	Mean daily concentrations of ulipristal acetate (mcg/L)	Mean daily concentrations of monodemethyl-ulipristal acetate (mcg/L)
0 - 24	22.7	4.49
24 - 48	2.96	0.62
48 - 72	1.56	0.28
72 - 96	1.04	0.17
96 - 120	0.69	0.10

Table 1. Mean daily concentrations of uliprisal acetate and its active metabolite, monodemethyl-ulipristal acetate in breast milk (3).

Case 5

- A 27-year-old breastfeeding mother was given an EllaOne tablet for emergency contraception.
- She is 2 months postpartum and fully breastfeeding.

- What advice would you give her regarding breastfeeding?

Acknowledgement:
Thank you to Dr Abigail Badrick for creating this comprehensive presentation

References

- https://www.fsrh.org/Public/News/Articles/Response-to-recent-member-enquiries-GLP-1-agonists-and-oral-contraceptives.aspx
- https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-ceu-statement-extended-use-of-all-52mg-lng-iuds-for-up-to-eight-years-for-contraception.pdf
- https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-ceu-statement-progresterogens-and-meningioma-roland-et-al-2024.pdf
- https://www.ajog.org/article/S0002-9378(22)00366-0/pdf
- https://www.ajog.org/article/S0002-9378(22)00729-3/pdf
- https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-ceu-statement-drsp-pop-janu24.pdf
- What is "Ozempic face" and how can people avoid it?
- Slynd® (drospirenone): Estrogen-Free Birth Control
- https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-statement-paternal-exposure-to-valproate.pdf

Key takeaways

- **52mg LNG-IUD Licensing:**
  - Extended for contraceptive use up to 8 years
  - Not applicable for HRT or heavy menstrual bleeding (HMB)
- **GLP-1 Agonists & Hormonal Contraception:**
  - Mounjaro® may reduce oral contraceptive effectiveness
  - Recommend non-oral contraceptives or barrier methods during initiation/dose adjustments
- **Sodium Valproate & Male Patients:**
  - Consistent condom use required while on treatment and for 3 months after stopping
- **EllaOne & Breastfeeding:**
  - No need to interrupt breastfeeding