## 令和4年1月24日 令和3年度医薬品等安全対策調査会 資料1-2

## 国内外の診療ガイドライン等における記載状況

## 1. 緊急避妊薬の投与前に妊娠していないことを確認する方法について

総説、診療ガイドライン等の名称	著者、団体名等	記載内容(抜粋)
産婦人科診療ガイドライン 婦人科外来編 2020	日本産科婦人科学会/ 日本産婦人科医会	CQ403 緊急避妊法の実施方法とその留意点は?解説 EC を行う際は問診にて、①最終月経の時期と持続日数、② 通常の月経周期日数から予 測される排卵日、③ 最初に UPSI があった日時とその際に使用した避妊法、④ UPSI があった期日以前の性交があった日時とその際の避妊法などについて確認し、現在の妊娠を否定するとともに、UPSI による今後の妊娠成立の可能性について評価することが必要である。
緊急避妊法の適正使用 に関する指針(平成 28 年度改訂版)	日本産科婦人科学会	第二章 緊急避妊薬(レボノルゲストレル単剤) (1) 処方前に行うべき問診と検査 問診では次のことを確認する。 ① 最終月経の時期と持続日数 ② 通常の月経周期日数から予測される排卵日 ③ 最初に UPSI があった日時とその際に使用した避妊法 ④ UPSI があった期日以前の性交があった日時とその際の避妊法 問診後、別紙1「緊急避妊薬(服用者向け情報提供資料)」などを用いて必要事項を説明する。インフォームドコンセントを得た証として、別紙2「同意書」に署名を求めてもよい。 なお、性暴力やコンドーム破損などでは性感染症なども起こり得ること、IUDをECとして使用する際は後に骨盤内炎症性疾患(PID)などの誘因と関連するかもしれないこと、および女性の健康に対する関心を高めるという観点から、必須ではないが、性感染症(Sexually Transmitted Infections: STI)のリスクについて説明し、機会をみてSTI検査や、加えて子宮腟部・頸部細胞診検査を受けることを勧める。

総説、診療ガイドライン等の名称	著者、団体名等	記載内容(抜粋)
EMERGENCY CONTRACEPTIVE PILLS - Medical and Service Delivery Guidance Forth Edition	the International Consortium for Emergency Contraception (ICEC) / the International Federation of Gynecology and Obstetrics (FIGO)	9. CLINICAL SCREENING Because ECPs are safe for all women and women can determine for themselves whether they have had unprotected or inadequately protected sex, no provider screening is needed before the use of ECPs. Clinical assessments (e.g., pregnancy tests, blood pressure measurements, laboratory tests, pelvic examination) are not necessary. ECPs are appropriate for over-the-counter, non-prescription provision.
Practice Bulletin, Emergency Contraception	(The American College of Obstetricians and Gynecologists (ACOG)	What screening procedures are needed before provision of emergency contraception?  No clinical examination or pregnancy testing is necessary before provision or prescription of emergency contraception. Emergency contraception should be offered or made available any time unprotected or inadequately protected sexual intercourse occurs and the patient is concerned that she is at risk of an unwanted pregnancy. Emergency contraception should not be withheld or delayed in order to test for pregnancy, nor should it be denied because the unprotected coital act may not have occurred on a fertile day of the menstrual cycle.

略号) EC: emergency contraception (緊急避妊法)、ECPs: emergency contraceptive pills (緊急避妊ピル)、IUD: intrauterine device (子宮内避妊具)、UPSI: unprotected sexual intercourse (避妊せずに行われた性交又は避妊したものの避妊手段が適切かつ十分でなかった性交)

2. 緊急避妊を目的としたレボノルゲストレル服用による児への影響/既に成立した妊娠に対する緊急避妊薬の投与について

総説、診療ガイドライン 等の名称	著者、団体名等	記載内容(抜粋)
実践 妊娠と薬 第2版	林 昌洋、佐藤孝道、北 川浩明	WI-5. 卵胞・黄体ホルモン 3 ヒト (疫学調査・症例報告など)

総説、診療ガイドライン 等の名称	著者、団体名等	記載内容(抜粋)
Contraceptive	Contraceptive	黄体ホルモン 〈レボノルゲストレル〉 緊急避妊のため性交後 72 時間以内にレボノルゲストレル単剤を服用した 979 例および、レボノルゲストレルとエチニルエストラジオールを服用した 976 例において、結果として出産に至った婦人の児に関して、児の奇形は報告されなかった。 Emergency Contraception
Technology 21th edition	Technology	Effects on future fertility and inadvertently exposed pregnancies. There is no evidence that ECPs have any long-term or adverse effects on fertility. One study of 332 pregnant women who had used LNG ECPs in the conception cycle found no increased risk of birth defects. Combined data from post-marketing surveillance and clinical trials of UPA found no teratogenic effects among 232 pregnancies with a known outcome in which the woman and conceptus were exposed to UPA. Moreover, two observations provide reassurance for any concern about birth defects. First, in the event of treatment failure, ECPs are taken long before organogenesis starts so, they should not have a teratogenic effect. Second, studies that have examines births to individuals who inadvertently continued to take combined oral contraceptives (including high-dose formulations) without knowing they were pregnant have found no increased risk of birth defects. For this reason, the FDA removed warnings about adverse effects of combined oral contraceptives on the fetus from contraceptive package inserts years ago.
WHO Medical eligibility criteria for contraceptive use 5th edition	World Health Organization (WHO)	9. Recommendations for use of emergency contraceptive pills, including adding the condition of obesity and the new method, ulipristal acetate  Recommendations For pregnant women, emergency contraceptive pill (ECP) use is not applicable. Although this method is not indicated for a woman with a known or suspected pregnancy, there is no known harm to the woman, the course of her pregnancy, or the fetus if ECPs are accidentally used.  Quality of the evidence Currently pregnant women

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4の石型		LNG-ECP use versus non-use of LNG-ECP; adverse pregnancy outcomes:	ery low
EMERGENCY CONTRACEPTIVE PILLS - Medical and Service Delivery Guidance Forth Edition	ICEC/ FIGO	7. EFFECTS ON PREGNANCY Studies of women who became pregnant despite using the LNG regimen or who used it inadvertently after becoming pregnant indicate that this regimen does not harm either a pregnant woman or her fetus. It does not increase rates of miscarriage, ectopic pregnancy, low birth weight, congenital malformations, or pregnancy complications. Postmarketing pharmacovigilance data collection for UPA ECPs also confirm the safety of this regimen. LNG and UPA ECPs are not indicated for women with a known or suspected pregnancy; however, there is no known harm to the woman, the course of her pregnancy, or the fetus if ECPs are accidentally used.	
		8. PRECAUTIONS AND CONTRAINDICATIONS ECPs are not indicated for a woman who has a confirmed pregnancy because they will have no benefit. However, if an evaluation for pregnancy has not been performed or if pregnancy status is unclear, ECPs may be used as there is no evidence to suggest harm to a developing fetus.	
Fact sheet on the safety of levonorgestrel-alone emergency contraceptive pills (LNG ECPs)	WHO	Can LNG ECPs harm a developing fetus?  LNG ECPs do not harm a developing fetus if they are mistakenly taken early in pregnancy. A study that compared pregnancy outcomes in women who used LNG ECPs during their conception cycle with women who had not used LNG ECPs found no differences in rates of miscarriage, birth weight, malformations, or in the sex ratio at birth.	
		Can LNG ECPs cause an abortion? LNG ECPs do not interrupt an established pregnancy or harm a developi The evidence available to date shows that LNG ECP use does not fertilized egg from attaching to the uterine lining. The primary me action is to stop or disrupt ovulation; LNG ECP use may also prevent and egg from meeting.	prevent a echanism of

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