



CLINICAL GUIDELINES
OBSTETRICS AND GYNAECOLOGY

CONTRACEPTION: ORAL CONTRACEPTIVES

COMBINED ORAL CONTRACEPTIVE PILL (COCP)

Keywords: COCP, contraception, oral contraceptive, the pill, birth control, contraceptive pill

Note: Click on the subjects below; the hyperlink will then take you to that section in the document.

Background: [Efficacy](#) [Contraindications](#) [Side-effects](#)
Management: [Prior to prescribing](#) [Initiation](#) [Counselling](#) [Follow-up](#)

AIM

- To guide staff on the [background](#), medication information, and management ([commencing](#), [counselling](#) & [follow-up](#)) of the combined oral contraceptive pill.

KEY POINTS

1. When taking the COCP women experience a withdrawal bleed rather than a menstrual bleed during the hormone-free intervals or placebo.¹
2. The COCP should not be prescribed in the first 21 days post-partum to avoid risk of thromboembolic complications. During the first 6 weeks postpartum, there is a 21.5 - 84 fold increase in VTE risk, with the highest risk in the first 21 days.²
3. Some medications may decrease efficacy of the COCP e.g. liver-enzyme inducing drugs, some antiepileptic drugs, antibiotics and St. John's Wort.² Advise methods of contraception that are not affected by liver enzyme inducing medications.²
4. A blood pressure (BP), body mass index (BMI) and detailed history should be conducted prior to prescribing the COCP.¹
5. Women prescribed the COCP should be advised of management should they miss/delay taking the pill/s, or if they have significant vomiting and diarrhoea.
6. All women prescribed the COCP should be advised of side-effects, risk factors, how to take the medication and follow-up with the medical practitioner.

BACKGROUND INFORMATION

COCPs are preparations of synthetic oestrogen and progesterone which inhibit ovulation, cause cervical mucus thickening, and may prevent implantation.³

Packaging consists of a minimum of 21 hormone pills followed by up to 7 days of placebo.² A bleed experienced during the hormone-free interval or placebo week is due to withdrawal of hormones rather than a menstrual bleed.¹ This means a 'fake' rather than 'real' period, with bleeding which is usually shorter and lighter than her normal period, and there is no physiological requirement to schedule a bleed every month.¹

COCPs are highly effective if used correctly, are easily reversible, and have been associated with improving acne, reducing risk for endometrial cancer, ovarian cancer,¹ and benign breast disease. The COCP can be used in management of premenstrual syndrome, reducing of functional ovarian cysts, and for management of polycystic ovarian syndrome.²

EFFICACY

- Perfect use results in 99.7% efficacy, while typical use results in 91% efficacy.²

CONTRAINDICATIONS²

Absolute contraindications²

- Breastfeeding and less than 6 weeks post-partum^{2, 4}
- Non-breastfeeding and <21 days post-partum, with additional venous thromboembolism (VTE) risk factors
- Age ≥35 years and smoking ≥15 cigarettes/day
- Current or history of ischaemic heart disease, stroke^{2, 4} (including transient ischaemic attack), and complicated valvular or congenital heart disease.
- Multiple risk factors for cardiovascular disease (e.g. smoking, obesity, older age, diabetes, hypertension)
- Hypertension:
 - Consistently raised blood pressure (BP - systolic ≥ 160 or diastolic ≥ 95 mmHg)^{1, 2}
 - With vascular disease
- Migraine with an aura at any age
- Past or present evidence of VTE^{2, 4} - deep vein thrombosis, pulmonary embolism, or known thrombogenic mutations.
- Major surgery with prolonged immobilisation.^{2, 4}
- On initiation: Active acute viral hepatitis flare or episode^{2, 4}
- Benign hepatocellular (adenoma) or malignant liver tumour, or severe (decompensated) cirrhosis.
- Reynaud's Disease- secondary with lupus anticoagulant.
- SLE- Positive (or unknown) antiphospholipid antibodies
- Current breast cancer^{2, 4}
- Diabetes (insulin & non-insulin dependent) complicated with nephropathy / retinopathy / neuropathy or other vascular disease, or diabetes duration > 20 years

Relative contraindications²

- Post-partum (Breastfeeding): Fully or almost fully breastfeeding from 6 weeks to 6 months post-partum
- Postpartum (Non-breastfeeding):
 - < 21 days post-partum, without additional VTE risk factors;
 - 21-42 days with additional risk factors for VTE
- Aged ≥35 years AND:
 - Stopped smoking <1 year ago; or
 - Currently smoking less than 15 cigarettes/day
- Hypertension:
 - Adequately controlled
 - Consistently raised BP (systolic 140 -159 or diastolic 90-94 mmHg)

- Past history of a migraine with an aura (none for 5 years); or migraine (without aura) develops during COC use.
- Symptomatic gall bladder disease: Current and/ or medically treated²
- Cholestasis- Past combined hormonal related
- Drug treatments affecting liver enzymes (e.g. some antibiotics, antiepileptic medications). Consider alternative contraception methods.
- Known hyperlipidaemias
- BMI $\geq 35\text{kg/m}^2$ ^{1, 2}
- Family history of venous thromboembolism in first-degree relative < 45 years
- Immobility unrelated to surgery
- Breast conditions:
 - History of breast cancer with no evidence of disease in the last 5 years
 - Undiagnosed breast mass at commencement of COC
 - Carrier of known gene mutations associated with breast cancer.

SIDE-EFFECTS²

These include:

- | | | |
|-----------------------------------|------------|---------------|
| • breakthrough bleeding | • headache | • weight gain |
| • breast tenderness | • nausea | • chloasma |
| • lowered libido and mood changes | • acne | • bloating |

RISKS²

The use of COCP has been associated with an increased risk of gall bladder disease, VTE, ischaemic stroke, myocardial infarct, and cervical cancer. Individual risks vary and are affected by co-existing morbidity and lifestyle factors.

MANAGEMENT: PRIOR TO PRESCRIBING

MEDICAL HISTORY²

Complete a medical history and check for [contraindications](#) prior to prescribing the COCP:

- Age:
 - Women under 18 years – complete a history of sexual activity and risk assessment. This includes confidentiality, legal issues, ability to consent, and child protection issues.
 - Women ≥ 40 years have a higher background risk of health conditions and should be carefully assessed for risk factors and gynaecological problems. Assess risk factors for cardiovascular and VTE
 - The COCP is not recommended for women ≥ 50 years, and other contraceptive methods should be used.

The woman (≥ 50) who is amenorrhoeic for 1 year using barrier methods, no longer requires contraception. However other contraceptive methods should be considered if the woman menstruates after ceasing COCP.²



- Pregnancy history: Abortion & miscarriage <24 weeks gestation
- Postpartum (birth ≥24 weeks) –breastfeeding history
- Self or family history for risk of thromboembolic disease
- Contraceptive history (previous types, side-effects, failures, preferences/ ability)
- Menstrual and vaginal bleeding history – exclude risk of pregnancy e.g. implantation bleed / ectopic
- Exclude risk factors and negative lifestyle factors e.g. cardiovascular, hypertension, thromboembolic disease, arterial disease, liver disease, cancer, smoking, obesity
- Assess for medications which may decrease the efficacy of the COCP e.g. rifampicin, some anti-epileptic drugs, and St. Johns Wart
- Migraine – women having migraines with an aura are at increased risk for strokes
- Cancer – COCP in the woman with breast cancer is contraindicated.

Note: Combined hormonal oral contraception is not associated with an overall increased risk of cancer, and in older women it is associated with a reduced overall risk of cancers. There is a small increase in the risk of cervical cancer with COC, however regular Pap smear screening can minimise this risk.

EXAMINATION

- Perform a BP. If raised, perform repeat measurements to confirm. Other contraceptive methods may be preferred in women with hypertension.²
- Perform cervical screening as required.¹
- Check for sexually transmissible infections as required.
- Calculate the woman's BMI.
A BMI >30 increases the VTE risk. See contraindications above if the BMI >35.²

INVESTIGATIONS²

- Women with risk factors for cardiovascular disease or aged over 40 years – consider testing fasting lipids and glucose if clinically indicated.
- Perform thrombophilia screening if a significant history of thromboembolic disease is evident or the woman has a first degree relative with known thrombophilia.

INITIATION OF COCP²

SITUATION	ACTIVE PILL COMMENCEMENT	EFFECTIVE
No contraception or barrier	Day 1 of the first day of bleeding in normal menstrual cycle to day 5. Any other time if pregnancy is excluded.	Immediately Effective within 7 days
Combined pill or vaginal ring	Begin the new packet on an active pill at the end of the pill free or ring free interval	Immediately
Depo-Provera [®] or Depo-Ralovera [®]	Anytime within 14 weeks of injection	Immediately
Implanon [®]	Anytime within 3 years of insertion	If commenced on the same day as Implanon is removed, allow 7 days to become effective
Progestogen only pills	If menstruates regularly, day 1 of the first day of bleeding in normal menstrual cycle to day 5. Anytime if pills have been correctly taken otherwise exclude pregnancy	Immediately Effective within 7 days
Abortion	Immediately (< day 5 post-procedure) If taken >5 days exclude repeat pregnancy	Immediately 7 days
Copper or Levonorgestrel IUD	If menstruates regularly, day 1 of the first day of bleeding in normal menstrual cycle to day 5. Other times: - condoms for 7 days prior to removal of the IUD, commence on day of removal - commence COCP 7 days before IUD removal	Immediately Effective within 7 days Immediately
Post-partum (not breastfeeding) - Includes stillbirth / termination >24 weeks gestation	If no menstrual cycle – any time after 3-6 weeks post-delivery and pregnancy is excluded If menstrual cycle resumed – follow instructions as above for no contraception or barriers	Effective within 7 days As above
Post-partum (breastfeeding) >6weeks	COC is not recommended under 6 weeks, and generally not recommended prior to 6 months post-partum. No menstrual cycle- anytime >6wks (exclude pregnancy) Menstrual cycle resumed - As above for no contraception or barriers	See: KEMH Clinical Guideline, O&G: Contraception: Postpartum 7 days As above

COUNSELLING

- Provide the woman with written information about the COCP, or refer her to Sexual & Reproductive Health WA (formerly the Family Planning of Western Australia) web site² at <http://www.srhwa.com.au/>
- Discuss the side-effects, risks and their warning signs, mode of action, administration, difference between hormone and placebo tablets, any temporary additional contraception required, expected bleeding patterns, and drug interactions of the COCP.²
- Management if a hormone pill is late or forgotten (missed)²:
 - If <24 hours late: Take the late hormone pill as soon as possible, then continue taking the pills as usual (2 pills can be taken on the same day). No additional contraceptive required
 - If >24 hours late: The most recent pill should be taken and previously missed pills discarded, then continue taking the pills as usual (2 pills can be taken on the same day). Additional contraceptive methods / abstinence are required until 7 consecutive active pills have been taken.
 - Missing more than 4 consecutive pills is classified as having 'stopped using the COCP' and the missed pill rules cannot apply. The woman should consider emergency contraception and commence a new packet.
 - Seven consecutive active/hormone pills are sufficient to suppress ovulation. The active pills closest to the placebo pills are the riskiest to miss.
 - If a pill is missed in the first 7 active pill days after the placebo, emergency contraception should be considered if there has been unprotected sexual intercourse in the past 5 days.
 - If the missed pills are in the last 7 days of active pills before the next placebo, the pill-free interval should be omitted.²
 - If the woman is unsure of how to manage when she misses a pill she should contact her prescriber or Family Planning Services.
- Inform the woman if she has significant vomiting within 2 hours or severe diarrhoea then the rule for missed pills should be applied.²
- A woman using antibiotics (that do not contain liver-inducing enzymes) does not require additional contraceptive measures.¹
- Women who do not wish to change their COCP contraception while having short-term treatment with an enzyme-inducing drug will need contraception review by the medical practitioner.¹
- Inform the woman to discuss with her medical practitioner the compatibility of the COCP with any new medications prescribed.
- Inform women to reduce periods of immobility during flights over 3 hours; and if staying or trekking at altitudes of >4500 metres for more than 1 week, to recommend avoiding COCP, and to use alternative forms of contraception.¹

FOLLOW-UP

1. Women at low risk for cardiovascular disease should be reviewed by a medical practitioner 4-6 months after commencement of the COCP,² then yearly. A recheck of the woman's medical history (including conditions such as migraine and lifestyle factors) should be attended at least annually.¹
2. Inform the woman to return for review anytime if any problems² (e.g. signs of side-effects, embolus, cardiovascular symptoms, or blood pressure symptoms).
3. On review, advise the woman to inform the medical practitioner of any side-effects, changes in her medical condition or bleeding patterns, commencement of new medications, adherence/ understanding of missed pills advice,² or of any future surgery. Attend a blood pressure and weight (if relevant).²

REFERENCES / STANDARDS

1. Faculty of Sexual and Reproductive Healthcare. **Combined hormonal contraception**. 2012. Available from: http://www.fsrh.org/pages/clinical_guidance.asp
2. Family Planning NSW, Family Planning QLD, Family Planning VIC. **Contraception: An Australian clinical practice handbook**. 3rd ed. Canberra: Sexual Health & Family Planning Australia; 2012. Available from: <http://contraceptionhandbook.org.au.kelibresources.health.wa.gov.au/acknowledgements-foreword/>
3. Guillebaud J, MacGregor A. **Contraception: Your questions answered**. 6th ed. Edinburgh: Churchill Livingstone Elsevier; 2013.
4. World Health Organization. Medical eligibility criteria wheel for contraceptive use. Geneva, Switzerland: **WHO**. 2015. Available from: http://apps.who.int/iris/bitstream/10665/173585/1/9789241549257_eng.pdf?ua=1

National Standards – 1- Care Provided by the Clinical Workforce is Guided by Current Best Practice
4- Medication Safety

Legislation -

Related Policies - KEMH Clinical Guidelines: Contraception

Other related documents –

- SRHWA (Patient Information Sheets): [Combined Oral Contraceptive Pill](#); [Contraception Choices](#)
- SRHWA (Health Professionals): [Contraception Essentials](#)
- WHO (2015) [Medical Eligibility Criteria Wheel for Contraceptive Use](#)

RESPONSIBILITY

Policy Sponsor	Nursing & Midwifery Director OGCCU
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