PROGESTOGEN ONLY ORAL CONTRACEPTION

Introduction

This method of contraception is suitable for any woman of childbearing age who wishes low dose oral hormonal contraception or who has contraindications to the use of oestrogens. It is available in a range of preparations and doses.

The primary mode of action of most progestogen only pills is to alter the cervical mucus making it inhospitable to sperm. There is also an effect on ovulation with anovulatory cycles reported in many women.

The desogestrel progestogen only pill (cerazette®) has been shown to inhibit ovulation in 97% of cycles and prevention of ovulation is its primary mode of action.

Efficacy

The failure rate for the POP is widely quoted as 0.3-3.0 per hundred women-years.
The percentage of unintended pregnancies in the first year of use is slightly higher than with a COC with a method failure rate of 0.5% compared with 0.1% for the COC. However, user failure rate pushes both up to 5%.

There is a higher reported pregnancy rate in women under the age of 35 i.e. 2.5/100 women first year of use, compared with 0.5/100 women first year of use in women aged over 35 years.

On theoretical grounds, the desogestrel only pill should have greater efficacy than other (traditional) POPs because of its effect of inhibition of ovulation. This has not been demonstrated in clinical practice. The theoretical improved efficacy may not provide further benefit to women whose natural fertility is already reduced.

There is no robust evidence base for decreased efficacy in heavier women. Faculty of Sexual and Reproductive Healthcare advice is that women over 70kg should be advised to take only one POP each day (traditional or Cerazette®).

Choice of Pill

Cerazette® is the first line choice in women under the age of 35 because of its effect on ovulation and its 12 hour 'window' with regard to missed pills.
Over the age of 35 efficacy data is high with all progestogen only pills and regular pill taking routine is predicted to be higher than in younger women. Therefore, the choice of cheaper preparations may be offered first line.

Brand name	Type of progestogen and dose	Cost per 3 x 28 tabs
Cerazette®	Desogestrel 75mcg	8.68
Femulen®	Ethynodiol diacetate 500mcg	3.31
Micronor®	Norethisterone 350mcg	2.11

Noriday®	Norethisterone	2.10
Norgeston®	Levonorgestrel 30mcg	2.21

Prices as MIMS May 2012

Common Side Effects (>1/100)

- Menstrual irregularities
- Skin disorders
- Breast tenderness
- Nausea

Less Common Side Effect (<1/100)

- Dizziness
- Mood disturbance
- Appetite disturbance
- Changes in libido
- There is insufficient data available to quantify any effect on risk of breast cancer

Drug Interactions

Women taking an enzyme inducer for >2 months should be advised to change to an alternative method. If short-term use (<2 months) is anticipated, the woman may continue use of POP and take additional precautions e.g. condoms whilst taking and for 28 days after discontinuing the enzyme inducer. Alternatively, she could be prescribed a one-off dose of progestogen-only injection to cover the period of risk.

Assessment of Client Suitability

History

Clinical history taking and examination allow an assessment of medical eligibility for POP use (see UKMEC criteria below). In this context the history should include: relevant social and sexual history (to assess risk of sexually transmitted infections – STIs), medical, family and drug history as well as details of reproductive health and previous contraceptive use.

Examination

- Blood pressure and BMI should be recorded prior to commencement of POP.
- Pelvic examination and cervical cytology only if indicated.

Documentation

- The full visit history should be completed or updated as required on NaSH.
- Written method information including contact number is given to client.
- Prescription is recorded and dated.
- Nurse supplying where appropriate under patient group direction.
- GP notified of prescription, if permission is given for correspondence.

CMSHN Draft Protocol **September 2012**

Starting Regimens for POP

Ensure client understands the method to aid satisfaction and compliance and knows to take one tablet daily at the same time.

1. **No Extra Precautions required if starting**:
    - Day 1 – 5 of the cycle.
    - Up to 21 days postpartum; lactation is not affected
    - Days 1-5 Post-termination or miscarriage.
    - While taking combined pill: change by instant switch (that is, without the COC pill-free interval).
    - While using Depo Provera if starting POP up to 13 weeks and 5 days since last injection
    - With an IUD, IUS or implant in situ (within licence limit).
      Remove the IUS/IUD/implant at least 7 days after starting the POP.
2. POP may be started at any time in the cycle if it is reasonably certain that the client is not pregnant, using additional contraceptive precautions for two days.
3. If a woman vomits within 2 hours of taking a POP then she should be advised to take another pill as soon as possible.

Missed Pills

Cerazette – Desogestrel

- If greater than 36 hours have elapsed since taking the last pill (i.e. > **12 hours late**) the late pill should be taken as soon as remembered.
- The next pill should be taken at the usual time
- Additional contraceptive precautions should be taken for the next **2** days[54]
- If unprotected sexual intercourse occurs in the time between the pill becoming late and 48 hours after recommencing the pill then consideration should be given to emergency contraception.

For All Other Progestogen Only Pills:

- If greater than 27 hours have elapsed since taking the last pill (i.e. > **3 hours late**) the late pill should be taken as soon as remembered
- The next pill should be taken at the usual time
- Additional contraceptive precautions should be taken for the next **2** days
- If unprotected sexual intercourse occurs in the time between the pill becoming late and 48 hours after recommencing the pill then consideration should be given to emergency contraception.

Follow Up Arrangements

Return Visit

Women may be offered up to 12 months of POP at her first and subsequent visit, with follow up yearly to ensure satisfaction and concordance with the method. Thereafter, there should be a flexible approach to contraceptive supply with ease of access should problems arise.

UKMEC	DEFINITION OF CATEGORY
CATEGORY 1	A condition for which there is no restriction for the use of the contraceptive method.
CATEGORY 2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
CATEGORY 3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method.
CATEGORY 4	A condition which represents an unacceptable health risk if the contraceptive method is used.

KNOWN THROMBOGENIC MUTATIONS (eg: Factor V Leiden; Prothrombin mutation; Protein S, Protein C and Antithrombin deficiencies)		2
SUPERFICIAL VENOUS THROMBOSIS		1
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE	I	C
	UKMEC CATEGORY	
	2	3
STROKE (history of cerebrovascular accident)	I	C
	2	n/a
KNOWN HYPERLIPIDAEMIAS (screening is NOT necessary for safe use of contraceptive methods)		2
VALVULAR AND CONGENITAL HEART DISEASE		
a) Uncomplicated		1
b) Complicated (e.g. with pulmonary hypertension, trial fibrillation, or a history of subacute bacterial endocarditis)		1
POST ABORTION		
a) First trimester		1
Neurological conditions		
HEADACHES	I	C
	UKMEC CATEGORY	
a) Non migrainous (mild or severe)	1	1
b) Migraine		
i. without aura, age <35 years	1	2
ii. without aura, age ≥35 years	1	3
iii. with aura, at any age	2	3
c) Past history of migraine with aura at any age	2	2
EPILEPSY – be aware of potential drug interactions		1
Depressive disorders		
DEPRESSIVE DISORDERS		1
Reproductive tract infections and disorders		
VAGINAL BLEEDING PATTERNS		
a) Irregular pattern *without* heavy bleeding		2
b) Heavy or prolonged bleeding (includes regular and irregular patterns)		2
UNEXPLAINED VAGINAL BLEEDING (suspicious for serious condition) before evaluation		2
ENDOMETRIOSIS		1
BENIGN OVARIAN TUMOURS (including cysts)		1
SEVERE DYSMENORRHOEA		1
GESTATIONAL TROPHOBLASTIC NEOPLASIA (GTN) (includes hydatidiform mole, invasive mole, placental site trophoblastic tumour)		
a) Decreasing or undetectable β-hCG levels		1
b) Persistently elevated β-hCG levels or malignant disease		1
CERVICAL ECTROPION		1
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)		1
CERVICAL CANCER (awaiting treatment)		2
Condition	UKMEC CATEGORY	

BREAST DISEASE		
a) Undiagnosed mass		2
b) Benign breast disease		1
c) Family history of cancer		1
d) Carriers of known gene mutations associated with breast cancer (eg: BRCA1)		2
e) Breast cancer		
i. Current		4
ii. Past and no evidence of current disease for 5 years		3
ENDOMETRIAL CANCER		1
OVARIAN CANCER		1
UTERINE FIBROIDS		1
PELVIC INFLAMMATORY DISEASE (past or current)		1
STIs		1
HIV/AIDS		
HIGH RISK OF HIV		1
HIV INFECTED		
a) Not using anti-retroviral therapy		1
b) Using anti-retroviral therapy		2
AIDS AND USING HAART- be aware of potential drug interactions		2
Other infections		
SCHISTOSOMIASIS		1
TUBERCULOSIS -be aware of potential drug interactions		1
MALARIA		1
Endocrine conditions		
DIABETES		
a) History of gestational disease		1
b) Non vascular disease		
i. non insulin dependent		2
ii. insulin dependent		2
c) Nephropathy/retinopathy/neuropathy		2
d) Other vascular disease or diabetes of >20 years' duration		2
THYROID DISORDERS		1
Gastrointestinal conditions		
GALL BLADDER DISEASE		
a) Symptomatic		2
b) Asymptomatic		2
HISTORY OF CHOLESTASIS		
a) Pregnancy related		1
b) Past COC related		2
VIRAL HEPATITIS	I	C
a) Active or flare	1	1
b) Carrier		1
c) Chronic		1
CIRRHOSIS		
a) Mild (compensated)		2
b) Severe (decompensated)		3
LIVER TUMOURS		
a) Benign (adenoma)		3
b) Malignant (hepatoma)		3
INFLAMMATORY BOWEL DISEASE (includes Crohn's disease, Ulcerative colitis)		2
Anaemias		
THALASSAEMIA		1
SICKLE CELL DISEASE		1
IRON DEFICIENCY ANAEMIA		1
RAYNAUD'S DISEASE		
a) Primary		1
b) Secondary		
i. *without* lupus anticoagulant		1
ii. *with* lupus anticoagulant		2

RHEUMATIC DISEASES	
SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) **People with SLE are at an increased risk of ischaemic heart disease, stroke and venous thromboembolism and this is reflected in the categories given.**	
a) Positive (or unknown) antiphospholipid antibodies	3
b) Severe thrombocytopenia	2
c) Immunosuppressive	2
d) None of the above	2

References

FFPRHC. Joint statement with CEU regarding off-label prescribing. December 2009

Faculty of Family Planning and Reproductive Health Care. Medical Eligibility Criteria For Contraceptive Use (UKMEC2009) Faculty of Family Planning and Reproductive Health Care, London 2009 www.ffprhc,org.uk

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. FFPRHC Guidance (July 2004) Contraceptive choices for breastfeeding women Journal of Family Planning and Reproductive Health Care 2004; 30(3): 181–195

FSRH Drug Interactions with Hormonal Contraception. January 2011

FFPRHC Progestogen-only pills. June 2009

With sincere thanks to the West of Scotland Sexual Health Managed Clinical Network for sharing their guidelines and protocols http://www.centralsexualhealth.org/west-of-scotland-managed-clinical-network