Northamptonshire Healthcare
NHS Foundation Trust

# MMPr004 COMBINED HORMONAL CONTRACEPTION PROTOCOL

## Table of Contents

## Why we need this protocol

The purpose of this protocol is to describe the process for Northamptonshire Integrated Sexual Health Service (NISH) staff to provide combined oral contraception within the clinics.

NISH welcome all clients and we respect all personal beliefs and life choices. We aim to serve everyone equally and we work hard to eliminate any disadvantages faced in respect to gender, age, ethnicity, disability, sexuality or any health inequalities. Carers/interpreters/chaperones are welcome to attend the consultation at the request of the client. The trust is happy to provide this service, although prior notification may be required.

## What the protocol is trying to do

The aim of this protocol is to describe the process for Northamptonshire Integrated Sexual Health Services (NISH) staff to provide combined hormonal contraception within the clinics.

## Which stakeholders have been involved in the creation of this protocol

Medicines Management Committee

## Any required definitions/explanations

NHFT - Northamptonshire Healthcare NHS Foundation Trust
MMC- Medicines Management Committee
BP – Blood pressure
LMP – Last Menstrual Period
CVD – Cardiovascular disease
BMI – Body Mass Index
FPA- Family Planning Association
INP- Independent Nurse Prescriber
FSRH – Faculty of sexual & reproductive healthcare
CHC – Combined Hormonal Contraception
VTE – Venous thromboembolism
NISH – Northamptonshire Integrated Sexual Health Service

## Key duties

### The Medicines Management Committee

Will review and approve the protocol

Is responsible for the implementation and dissemination of this protocol

### Medical Director

Is responsible for the dissemination of this protocol as appropriate to their Clinical Director's and Clinical Tutor's

### Clinical Director's

Are responsible for the dissemination and implementation of the protocol in their service areas as appropriate

### NISH staff

Are responsible for following this protocol when providing contraceptive care within the clinics.

## Protocol detail

## Client attends clinic / venue

**History: Take a history and document this in client record, ensuring that valid consent is obtained and documented.**

Minimum history to be taken:

□ Age

□ LMP

□ Personal medical history:

- Risk factors for arterial disease including smoking, diabetes and hypertension;
- History of migraine +/- aura (focal symptoms);
- Risk factors for thromboembolism;
- Exclude relevant medical history (including liver disease, cholecystitis, breast cancer, porphyria, abnormal vaginal bleeding, etc);

□ Family history;

- VTE (especially in first degree relative <45 years old);
- Breast cancer;
- Arterial disease (eg stroke/MI especially in 1st degree relative < 45 years old);

□ Drug history;

- Use of prescription or over the counter medication including current or recent use of liver enzyme inducing drugs;
- Any known allergies

Examination: Record BP, weight (in kg), height (in cm's) and BMI

CHC to be prescribed by doctor or nurse prescriber or issued under PGD. (PGD number 107).

Give the current FPA COC, Contraceptive Patch or Contraceptive Vaginal Ring leaflet as appropriate**.**

### Providing information for clients taking Combined Hormonal Contraception

Go through leaflet with client making sure she understands the following:

- The type of hormonal contraception she has been given
- Efficacy
- Starting regime
- Pill/patch/ring teach (how to take, hormone free duration, withdrawal bleed, when to re-start )
- Benefits
- Common side effects
- Safety – risk of VTE, arterial disease, breast cancer, cervical cancer
- What to do if:

    a) she has sickness or diarrhoea

    b) misses pills or replaces her patch or ring late – advice as per FSRH guidance, August 2012

- Drug interactions ( liver enzyme inducers including St Johns Wort)
- Safer sex (offer condoms)

- Advise to return before scheduled appointment if any concerns or if there is a change in personal/family history.

### Repeat visits and follow up

Interval of repeat visits -

- 3 months after first starting or changing CHC, 6 months if an established user but new to the service
- Then 6 months (3 for a minor)
- The nurse or doctor at their discretion may wish to see a patient in 1 month
- Clients must be advised to seek advice between planned visits if they have any concerns or develop major illness, migraine (or worsening thereof) take new medication or if a first degree relative develops cardiovascular or thromboembolic disease before age 45 or breast cancer.

At each planned visit:

- Review: satisfaction with method, new symptoms, bleeding patterns, changes to medical history, family history, drug history
- BP
- Weight (in kg) and BMI
- Offer condoms
- CHC to be prescribed by doctor or nurse prescriber or issued under PGD. (PGD number 107).

### Changing pills

Have no break and start new pill (patch or ring) immediately after the last pill of the present strip. No additional contraception is needed. If already on pill free interval (PFI) start pills (patch or ring) immediately and use condoms for seven days.

### Checklist for dispensing hormonal contraception

- Dispense by nurse or doctor. Check the expiry date. It is good practice that a second person checks that the supply given is correct, although it is understood this is not always possible. This should be documented in patient records (if applicable).
- Boxes of pills should be labelled with the appropriate product specific pre- printed medicine label (that states the name of medication and instructions for use) which nurse or doctor adheres to the box and completes with patients' name, quantity supplied, the date and initials of clinician issuing and placed in a bag.

## Training requirements associated with this protocol

### Mandatory Training

There is no mandatory Training associated with this protocol

### Specific Training not covered by Mandatory Training

Ad hoc training sessions based on an individual's training needs as defined within their annual appraisal or job description. All nurses and doctors working under this protocol will hold a relevant Contraception and Reproductive Healthcare qualification

## How this protocol will be monitored for compliance and effectiveness

The table below outlines the Trusts' monitoring arrangements for this document. The Trust reserves the right to commission additional work or change the monitoring arrangements to meet organisational needs.

| Aspect of compliance or effectiveness being monitored | Method of monitoring | Individual responsible for the monitoring | Monitoring frequency | Group or committee who receive the findings or report | Group or committee or individual responsible for completing any actions |
|---|---|---|---|---|---|
| Duties | To be addressed by the monitoring activities below. | | | | |
| Protocol process followed | Audit of 50 patients records from across the service | NISH Contraceptive Lead Clinician | Every 2 years | NISH Contraceptive Lead Clinician MMC | NISH Senior Nurse |
| Where a lack of compliance is found, the identified group, committee or individual will identify required actions, allocate responsible leads, target completion dates and ensure an assurance report is represented showing how any gaps have been addressed. | | | | | |

## Equality considerations

Refer to MMP001 Control of Medicines Policy

## Reference Guide

- Combined Hormonal Contraception – FSRH, August 2012 www.fsrh.org.uk
- Combined Hormonal Contraception – Missed Pills, FSRH, August 2012 www.fsrh.org.uk
- Quickstarting Contraception, FSRH, April 2017 www.fsrh.org.uk
- FSRH Clinical Guidance: Problematic Bleeding with Hormonal Contraception – FSRH July 2015 www.fsrh.org.uk
- CEU Clinical Guidance: Drug Interactions with Hormonal Contraception FSRH November 2017 www.fsrh.org.uk
- UK Medical Eligibility Criteria for Contraceptive Use April 2016 www.fsrh.org.uk
- NMC Standards for Medicines Management August 2008
- PGD 107 Combined Oral Contraception

## Document control details

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|---|---|
| **Author:** | Dr Sophie Herbert GUM Consultant<br>Dr Rosalind Phillips Clinical Lead for Contraception |
| **Approved by and date:** | Medicines Management Committee – September 18 |
| **Any other linked Policies:** | MMP001 Control of Medicines |
| **Protocol number:** | MMpr004 |
| **Version control:** | Version 2.0 |

| Version No. | Date Ratified/ Amended | Date of Implementation | Next Review Date | Reason for Change (eg. full rewrite, amendment to reflect new legislation, updated flowchart, minor amendments, etc.) |
|---|---|---|---|---|
| 1.0 | 19.07.16 | 19.07.16 | 31.07.18 | Review |
| 2.0 | 11.09.18 | 11.09.18 | 30.09.20 | Minor amendments to allow applicability to all CHC not just combined oral contraception |
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## Appendix 1 - Guidance

Below is the list / guidance for combined hormonal contraception methods that can be issued / prescribed at NHFT contraceptive clinics. Clinicians are encouraged to use their clinical judgement on deciding the most suitable product for the individual woman.

| Brand Name | Contraceptive Formulation | Use Status | Comments – Conditions for use |
|---|---|---|---|
| **1**. Microgynon 30®, (also available as Elevin®, Erlibelle® Maexeni®, Levest®, Ovranette®,Rigevidon®) | Ethinylestradiol 30µg<br>Levonorgestrel 150µg | First Line | ▪ Existing user<br>▪ New clients commencing CHC |
| **2.** Microgynon 30 ED® | Ethinylestradiol 30µg<br>Levonorgestrel 150µg<br>White inactive pills x 7 | If conditions for use fulfilled, may be used as first line | ▪ Existing user<br>▪ Everyday pill preferred<br>▪ Likely to aid compliance |
| **3.** Mercilon®, (also available as Gedarel® 20/150, Lestramyl® 20/150 Munalea 20/150®,) | Ethinylestradiol 20µg<br>Desogestrel 150µg | If conditions for use fulfilled, may be used as first or second line | ▪ Existing user<br>▪ Requests 20µg pill (and aware of more stringent missed pill rules)<br>▪ Can be used as second line if 20µg CHC pill needed in patients who have oestrogenic side effects with a 30mg COC (e.g. nausea, headache, breast symptoms, increased vaginal discharge)<br>▪ Accepts VTE risk |
| **4.** Cilest® (also available as Lizinna®) | Ethinylestradiol 35µg<br>Norgestimate 250µg | Second Line | ▪ Existing user<br>▪ Intolerant to first line product<br>▪ Acne develops or exacerbates on first line CHC |
| **5.** Marvelon, also available as Alenova®, Cimizt®, Gedarel® 30/150, Lestramyl® 30/150, Munalea® 30/150, | Ethinylestradiol 30µg<br>Desogestrel 150µg | Second Line | ▪ Existing user<br>▪ Acne develops or exacerbates on first line drug<br>▪ Accepts VTE risk<br>▪ Can be used as third line CHC if patient develops |

| Brand Name | Contraceptive Formulation | Use Status | Comments – Conditions for use |
|---|---|---|---|
| | | | progestogenic side effects on 1st & 2nd line CHC (e.g. mood change, depression, vaginal dryness) |
| **6.** Femodene®, Aidulan® 30/75 Katya® 30/75, Millinette® 30/75 | Ethinyloestradiol 30µg<br>Gestodene 75µg | Third line | Existing user<br>▪ Intolerant to second line product<br>▪ For better cycle control (Break Through Bleeding (BTB) with 1st/2nd line CHC and no other cause for BTB found)<br>▪ Accepts VTE risk |
| **7.** Femodette®, Aidulan® 20/75, Millinette® 20/75, Sunya® 20/75 | Ethinylestradiol 20µg<br>Gestodene 75µg | Third line | ▪ Existing user<br>▪ Requests 20µg pill (and aware of more stringent missed pill rules)<br>▪ Intolerant to other 20µg COC<br>▪ Accepts VTE risk |
| 8. Loestrin 30® | Ethinylestradiol 30µg<br>Norethisterone acetate 1.5mg | Third line | ▪ Existing user<br>▪ Intolerant to second line product<br>▪ Heavy withdrawal bleeds on other COC |
| 9. Loestrin 20® | Ethinylestradiol 20µg<br>Norethisterone acetate 1mg | Third line | ▪ Existing user<br>▪ Requests 20µg pill (and aware of more stringent missed pill rules)<br>▪ Intolerant to other 20µg COC |
| | | | |
| 10. Yasmin® (also available as Cleosensa®, Lucette®) | Ethinylestradiol 30µg<br>Drospirenone 3mg | Other | ▪ Existing user<br>▪ Acne develops or exacerbates on 1st or 2nd line COC<br>▪ PMS (pre menstrual syndrome) symptoms on other COC<br>▪ Symptoms of fluid retention develops with other COC (e.g. Cyclical breast enlargement) |
| | 6 Tablets containing | | |

| Brand Name | Contraceptive Formulation | Use Status | Comments – Conditions for use |
|---|---|---|---|
| 11. Logynon®,TriRigol® | Ethinylestradiol 30µg &Levonorgestrel 50µg<br>Ethinylestradiol 40µg &Levonorgestrel 75µg<br>Ethinylestradiol 30µg &Levonorgestrel 125µg | Other | ▪ Existing user<br>▪ For a better bleeding pattern (if bleeding pattern not settled with Femodene or Cilest)<br>▪ Absent withdrawal bleed with other COC |
| 12. Evra | Ethinylestradiol with Norelgestromin Cutaneous patch | Other | • Existing user<br>• To aid compliance where a patch is preferred by the patient<br>• Oral route less appropriate e.g eating disorder, active Inflammatory Bowel Disease |
| 13. Nuvaring | Ethinylestradiol with etonogestrel 0.12mg/0.015mg per day vaginal delivery system | Other | • Existing user<br>• To aid compliance where a vaginal ring is preferred by the patient<br>• Intolerant to oral preparation<br>• Oral route less appropriate e.g. eating disorder, active Inflammatory Bowel Disease |