Medical Management of Miscarriage Protocol (CG621)
Up to 14 weeks gestation (CRL = 84mm)

Approval

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<tr>
<th>Approval Group</th>
<th>Job Title, Chair of Committee</th>
<th>Date</th>
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<td>Gynaecology Clinical Governance</td>
<td>Chair, Gynaecology Clinical Governance</td>
<td>15th February 2019</td>
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Change History

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<th>Version</th>
<th>Date</th>
<th>Author, job title</th>
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<td>KM Smith, J Waite, Consultant Gynaecologist</td>
<td>Emergency Gynae requirement</td>
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<td>KM Smith, J Waite, W Kuteesa Consultant Gynaecologist</td>
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<td>W Kuteesa, Dalia Sikafi, Abdul Wagley Consultant Gynaecologist</td>
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<td>B Chohan, Consultant Obs &amp; Gynae</td>
<td>Reviewed in line with current NICE guidelines</td>
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<td>4.1</td>
<td>Feb 2019</td>
<td>B Chohan, Consultant Obs &amp; Gynae</td>
<td>Live change as result of RCA – pg 7 para added re: sending POC to Oxford if 3rd consecutive miscarriage</td>
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Author: B Chohan
Date: March 2019
Job Title: Consultant Obs & Gynae
Review Date: February 2021
Policy Lead: Group Director Urgent Care
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This document is valid only on date printed
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Other relevant corporate or procedural documents:
- Management of First Trimester Miscarriage Protocol (CG656).
1.0 Purpose
To assist medical and nursing staff in the use of Misoprostol for the medical management of miscarriage.

2.0 Scope
- Emergency Gynaecology Clinic
- Emergency Gynaecology Clinic Staff

3.0 Roles and Responsibilities
- Consultant Lead for Emergency Gynaecology/Early Pregnancy Clinic
  - To ensure that all junior doctors understand the content of the protocol and are able to follow the guidelines in ensuring that patients are managed sensitively and effectively through this process.
  - To work with lead nurse to ensure that the protocol is reviewed regularly and updated to reflect any changes to current guidance.
- Lead Sister for Emergency Gynaecology/Early Pregnancy Clinic
  - Co-ordinate training of all staff to ensure that protocol is utilised effectively
  - To ensure that all patients within the Emergency Gynaecology Clinic and/or ward who are diagnosed with an early miscarriage are given appropriate support and guidance through diagnosis and treatment
  - To work alongside Consultant Lead to review protocol regularly and update as necessary to reflect changes in current national guidance.
- All Doctors and Nurses working within the Gynaecology Unit
- All staff to provide competent, effective and compassionate care for women diagnosed with a miscarriage

4.0 Introduction
This protocol guides the use of misoprostol in the medical management of miscarriage (mainly missed miscarriage) before the 14th week of pregnancy (CRL=84mm). Misoprostol is a synthetic prostaglandin analogue that induces uterine contractions resulting in the evacuation of uterine contents. Do not offer mifepristone as treatment for missed or incomplete miscarriage.

Please read this protocol in conjunction with the Management of First Trimester Miscarriage Protocol (CG565).
4.1 Indications:

4.2.1 Missed miscarriage
Medical management should be offered as a treatment option in addition to offering expectant and surgical management (SMM).

4.2.2 Benefits of medical management for missed miscarriage:
- Fewer patients (20%) require SMM compared to those undergoing expectant management (30%).
- Fewer emergency admissions than expectant management.
- Avoids surgical/anaesthetic risks.
- Faster, more predictable commencement of bleeding (after administration of drugs) than expectant management for missed miscarriage. Bleeding usually starts within 24 hours of medical management.

4.2.3 Patients unlikely to benefit from medical management:
1. Medical management is less likely to be successful after failed expectant management.
2. Gestations over 10 weeks (CRL >31mm by ultrasound). Can be offered with advice about risk of heavier bleeding than during SMM.
3. Incomplete miscarriage
Do not routinely offer medical management for incomplete miscarriage in the first trimester - There is no advantage over expectant management (no difference in time to resolution).
During expectant management of incomplete miscarriage, the miscarriage is usually complete (80%) within 3 days.
This does not mean that medical management is contraindicated. Some women will have a strong preference for medical management despite counselling. Under these circumstances discuss with the consultant on call for possible medical management.

4.2 Contraindications to medical management:
1. Heavy bleeding (subjective assessment by clinician).
2. Haemoglobin <10g/dl (bleeding risk for expectant/medical management).
3. Severe pain.
4. Pyrexia > 38°C (possible infected products of conception).
5. Anti-coagulant therapy (bleeding risk).
7. Porphyria.
8. Mitral stenosis.
9. Severe asthma.
10. IUCD in-situ (coil must be removed before administration of misoprostol).

4.3 Information for Patients:

4.3.1 Pre-consent counselling.
- Medical management shortens the time to commencement of missed miscarriage but not the time to completion.
- Even during successful medical management, light bleeding may persist for up to 3 weeks.
- Expect heavy bleeding and cramping pains for 24-48 hours after misoprostol administration. A member of the nursing staff will call the next day to confirm the onset of bleeding and check well-being.

4.3.2 Misoprostol side effects are fairly common and include:
- Nausea and vomiting - resolve within 2-6 hours.
- Diarrhoea - resolves within 24 hours.
- Pyrexia and fever - resolve within 12 hours.
- Skin rash - resolves within 2-3 days.

4.3.3 Off-label prescribing of Misoprostol.
- Misoprostol, is not licensed (off-label) for medical management of miscarriage.
- It is licenced for other conditions such as treating gastric ulcers.
- The doctor must document that the patient is aware that misoprostol is not licensed for the treatment of miscarriage and obtain the patient’s written consent.
- Explain that off-label treatments are fairly common (most medicines administered to children are off-label) in medicine and that misoprostol is effective and safe in selected patients and is recommended by NICE.

4.3.4 Further advantages/disadvantages compared to the alternative management options:

Medical management:
- Greater side effect profile than expectant and surgical management.
- No difference in the duration of pain or bleeding cf. expectant management.
- Longer duration of pain and bleeding than SMM.
- There is no difference in infection rates (1-3%) cf. expectant and surgical management.
- No difference in future pregnancy rates cf. expectant and surgical management.
4.4 Medical management of miscarriage pathway:

1. Counsel patients on the advantages, disadvantages and alternatives to medical management.
2. Provide information leaflets on miscarriage and medical management.
3. Give the patient time to decide and the option to return at a later date for treatment.
4. Treatment should be commenced Monday – Wednesday. This should enable the 602 emergency clinic to manage the patients to minimise impact on the inpatient ward over the weekend.

If the patient decides on medical management:

5. Provide the Medical Management of Miscarriage Patient Instruction Leaflet.
6. Obtain written consent for medical management, include:
   - Failure / SMM rates (approx. 20%).
   - Misoprostol is unlicensed for this indication.
   - Side effects.
   - Pain, potential heavy bleeding.
7. Document:
   - Temperature
   - Blood Pressure
   - Pulse
8. Take blood for:
   - FBC
   - G&S

Anti-D should not be administered to women undergoing medical management of miscarriage under 12 week’s gestation.

Dispense 800μg Misoprostol for the patient to administer vaginally at home or to be administered by nursing staff prior to discharge depending on patient choice.

4.5 Advice to patients who decide on medical management

4.5.1 Advice to patients: Misoprostol administration.
- Insert the misoprostol on the next morning at home (Monday – Wednesday).
- Pass urine before inserting misoprostol with fingers or a tampon.
- Eat and drink as normal.
- Use sanitary towels rather than tampons after inserting misoprostol.
- Lie down for 30-60 minutes after vaginal insertion.
- **Reinsert** tablets vaginally if they fall out.
- The 800μg misoprostol tablets can be taken orally but may be less effective (NICE 2012); this is why we advise **vaginal** administration.
- Paracetamol +/- ibuprofen analgesia.
- If nausea and vomiting are severe, patient may call and return for anti-emetics.

**Misoprostol is an abortifacient** - It must be made clear to patients to:
- **Not keep** misoprostol tablets or give them to anyone else.
- To **return** any **unused** misoprostol tablets to the ‘602’ clinic or any pharmacy.

4.5.2 Misoprostol advice to patients: What to expect post-administration.
- Make sure the patient is aware of our **24-hour contact number** (included in the patient information leaflet).
- If heavy bleeding or products of conception (POC) are **not seen** in the **first 24 hours** after taking PV misoprostol, call the ‘602’ clinic for further advice.

*Inform on-call consultant - management options are then:*
1 - **Expectant management**
2 - **Surgical management**
3 - Dispense a further **600μg** dose of misoprostol to be taken PV on the **next morning**.

**Disposal of products of conception (POC).** Please read the protocol and provide the leaflet on ‘Sensitive Management of Pregnancy Tissue’.

Blood clots may be disposed of as normal.

Patients may decide to:
- Bring the pregnancy remains to the 602 Clinic for histology and sensitive disposal (patient will need to give written consent for this).
- Organise a private burial or cremation.
- Legally bury POC on private land when adhering to the regulations.

**If this miscarriage is the third consecutive miscarriage, offer for the POC to be sent to Oxford for cytogentics, if this has not already been done in the past. You must add ‘testing for cytogenetics’ to the consent form. If POC are being sent for cytogentics, they must not be sent in formalin and some POC must still be sent for histology.**
4.5.3 Advice on when else to call the 602 clinic:

- Any concerns.
- Prolonged or severe side effects.
- Prolonged (>3 days) heavy bleeding (flow not subsiding).
- Haemorrhage (clots the size of a palm or soaking sanitary pads every 20 minutes).
- Symptoms of haemodynamic instability or infection.
- Persistent bleeding for more than 3 weeks.

Positive home pregnancy test after 3 weeks.

4.5.4 Follow-up:

1. No routine follow-up unless clinically indicated.
2. Patient to be given 24-hour contact number.
3. If the bleeding stops, the patient should perform a home urine pregnancy test 3 weeks later and advised to call 602 clinic if the test is positive.
4. Reasons for clinic follow up:
   - Patient requests SMM.
   - Bleeding persists for >3 weeks.
   - +ve home urine pregnancy test 3 weeks later.
   - Patient request.

5.0 Medical management of Miscarriage as an inpatient:

- Inpatient management should be offered to patients who request it or for those measuring greater than 9 weeks gestation fetus size (> 21mm) due to the risk of heavier bleeding.
- A side room should be made available on Sonning ward for these patients to maintain privacy.
- The medical management of miscarriage pathway will be completed after written consent is taken.
- MEWS observations should be taken on admission and continued every 4 hours. If any changes occur in the patient’s clinical condition then the frequency of the MEWS must be reassessed.
- On admission 800 micrograms of Misoprostol vaginally will be administered by the patient, nurse or duty doctor.
- A further 600 micrograms of misoprostol vaginally will be administered after 3 hours if no products of conception are passed.
- Patients can be discharged once the products of conception are passed, bleeding is not heavy and observations are stable.
- If no products of conception are seen and the pain and bleeding have settled, the patient may be allowed home with an ultrasound scan in the 602 clinic within 48 hours.
- If medical management fails surgical management may be offered.

6.0 Consultation Undertaken
- Emergency Gynaecology and Sonning Ward Sisters
- Gynaecology Clinical Governance Committee – This includes: a patient representative, Gynaecology Operations Managers, Gynaecology consultants, Junior and middle grade medical staff.
- A copy of the protocol was circulated to all stakeholders for amendments prior to a scheduled clinical governance meeting.

7.0 Dissemination/Circulation/Archiving
- A hard copy will be kept in the Emergency Gynaecology clinic and on Sonning Ward.
- A hard copy will be given to all junior medical staff at induction.
- Copy will be e-mailed all medical staff.
- Protocol will be available on the Trust intranet Policy Hub (Gynae protocol section) and external website.
- The Trust Secretary will be responsible for archiving old versions of this document.

8.0 Implementation
Medical and nursing staff will be reminded of protocol by the Emergency Gynaecology Sister and the Gynaecology consultants.

9.0 Training
There is no mandatory training associated with this procedure. If staff have queries about its operation, they should contact their line manager in the first instance.

Author: B Chohan
Date: March 2019
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10.0 Monitoring of Compliance

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<th>Monitoring method</th>
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<th>Committee/individual responsible for ensuring that the actions are completed</th>
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The Trust reserves the right to amend its monitoring requirements in order to meet the changing needs of the organisation.

11.0 Supporting Documentation and References


5. British National Formulary 60 (September 2010).


12.0 Equality Impact Assessment

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Name of Protocol: Management of 1st Trimester Miscarriage Protocol

Do different groups (age, disability, race, sexual orientation, gender, religion or belief) have different needs, experiences, issues and priorities in relation to the proposed protocol?

NO

Is there potential for or evidence that the proposed policy will not promote equality of opportunity for all and promote good relations between different groups (age, disability, race, sexual orientation, gender, religion or belief)?

NO

Is there potential for or evidence that the proposed policy will affect different population groups (age, disability, race, sexual orientation, gender, religion or belief) differently (including possibly discriminating against certain groups)?

Affects women of reproductive age only

Is there public concern (including media, academic, voluntary or sector specific interest) in potential discrimination against a particular population group or groups (age, disability, race, sexual orientation, gender, religion or belief)?

NO
Appendix 1 - Flow chart for medical management of miscarriage as an OUTPATIENT:

- Patient counselled
- Information leaflets given
- Obtain written consent for procedure and products of conception.
- Inform 602 nurse
- FBC/G&S (Ensure Hb >100g/l)

Dispense misoprostol 800mcg PV for patient to take at home or insert prior to discharge. Patient called by nursing staff next day to check bleeding and well-being.

Expectant Management - Patient choice

No products of conception passed

Repeat treatment with misoprostol 600mcg PV in 24 hours - patient choice

Products of conception passed completely

Surgical Management – Patient choice

Discharge and advise woman to perform urine pregnancy test 3 weeks following passage of products of conception.

If UPT positive or if symptomatic (pain and bleeding) – Patient to self-refer back to 602 clinic for assessment by doctor +/- US scan.
Appendix 2 - Flow chart for medical management of miscarriage as an INPATIENT:

- Recommended for gestations > 9 weeks gestation (  
  
  - Patient counselled
  - Information leaflets given
  - Obtain written consent for procedure and sensitive management for products of conception.
  - Inform 602 nurse
  - Arrange date for treatment
  - FBC/G&S (Ensure Hb >100g/l)
  - Anti D if Rh neg (>12 weeks)

  - Arrange side room to ensure privacy
  - Prescribe misoprostol 800mcg to be inserted vaginally by patient, nurse or duty doctor

- No products of conception passed
  - Repeat treatment with misoprostol 600mcg PV in 3 hours
  - If still no POC passed but bleeding not heavy allow home on same day and arrange **US scan** within 48 hrs in 602 clinic. Offer date for **SMM** within 7 days.

- Products of conception passed completely (send to lab)

**Discharge** and advise woman to perform urine pregnancy test 3 weeks.

If UPT positive or if symptomatic (pain and bleeding) or if bleeding for more than 3 weeks – to self-refer back to 602 clinic for assessment by doctor +/- US scan.