

Threatened Miscarriage: Management

Version 4.2

Lead Person(s): Guy Calcott, Consultant Gynaecologist
Reviewed by: Kerry Redge, Lead EPAS Clinical Nurse Specialist
Care Group: Women's and Childrens Services
First Implemented: February 2005
This Version Implemented: 20th May 2024
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Keywords: Pregnancy, viable, Miscarriage
Written by: Guy Calcott, EPAS Lead Consultant
 Alex Keene, Specialist Nurse EPAS
Consultation: Clinical Governance Group
Comments: References to SaTH Guidelines in the text pertain to the latest version of the Guideline on the intranet.
 Printed copies may not be the most up to date version.

For Triennial Review

Version	Implementation Date	History	Ratified By	Full Review Date
1	February 2005		Gynae Clinical Governance	April 2009
2	24 th June 2011			June 2014
3	20 th January 2016	Full review		Jan 2019
3.1	16 th July 2019	Full review – just a date change	Lead Alex Keene	16 th July 2022
4	17 th November 2022	Full re-write and name changed previously Management of Viable Pregnancy	Clinical Governance	17 th November 2025
4.1	12 th May 2023	Appendix 4 – Auditable standards added		17 th November 2025
4.2	20 th May 2024	-Changes from Utrogestan to Progesterone - Added Cyclogest - Added appendix 4 & 5 Reviewed by Kerry Redge, Lead EPAS Clinical Nurse Specialist	Gynae and Fertility Clinical Governance	17 th November 2025

1.0 Introduction

- 1.1 The experience of pregnancy is different for each individual woman and couple.
- 1.2 During pregnancy physical and emotional changes take place and individuals have different needs which should be met in a caring and sensitive environment.
- 1.3 NICE guidance was updated in 2021 following the publication of the PRISM trial.
- 1.4 Based on a systematic review of research studies, including the PRISM trial, it includes new recommendations on the use of progesterone for women who have vaginal bleeding in early pregnancy and have had one or more previous miscarriages.
- 1.5 The NICE guidance does not recommend progesterone treatment for women who have vaginal bleeding in early pregnancy but have not had a previous miscarriage, or women who have had one or more previous miscarriages but don't have any vaginal bleeding during early pregnancy.

2.0 Aims

The aim of this guideline is to aid the prompt diagnosis of a viable intrauterine pregnancy and to provide a framework for the appropriate management, in patients who are referred with bleeding or pain in early pregnancy.

3.0 Objectives

- 3.1 Prevent delay in early diagnosis.
- 3.2 Provide appropriate health education as soon as possible.
- 3.3 Advise on routine care.
- 3.4 Provide physical and emotional support.
- 3.5 To provide treatment in an attempt to reduce the risk of miscarriage.

4.0 Definitions

- 4.1 **Viable Pregnancy** - Crown rump length with fetal heart identified on ultrasound scan.
- 4.2 **Threatened Miscarriage** – Early pregnancy bleeding in a patient with a confirmed viable pregnancy or pregnancy of uncertain viability.
- 4.3 **M.I.S:** Maternity Information System (Badgernet)

5.0 Process

5.1 Management

- Confirm positive pregnancy test (urine/blood).
- MIS episode created.
- Ultrasound scan.
- Discuss scan findings.
- Take full clinical history including past obstetric history
 - Consider use of Progesterone if previous miscarriage (see below) and patient presenting with bleeding.
 - If commences Progesterone (Utrogestan or Cyclogest) to send standard letter to GP (See Appendices)
- Health education advice eg. Folic acid, smoking, diet, alcohol, general health, pain and bleeding (with relevant information leaflets) to be given to all women.
- Advise a woman with a confirmed intrauterine pregnancy with a fetal heartbeat who presents with vaginal bleeding, but has no history of previous miscarriage, that:
 - if her bleeding gets worse, or persists beyond 14 days, she should return for further assessment
 - if the bleeding stops, she should start or continue routine antenatal care.
 - Women with bleeding in the second trimester (beyond 12 weeks) should be discussed with the early pregnancy consultant. These women may need to be considered for a higher risk antenatal care pathway because of a higher risk of perinatal morbidity and mortality (Harlev 2008)
 - For women with recurrent bleeding, a speculum examination should be

performed, if not already done so to look for local causes (eg cervical cancer)

- Offer vaginal micronised progesterone 400 mg twice daily to women with an intrauterine pregnancy confirmed by a scan (see 5.2), if they have vaginal bleeding and have previously had a miscarriage.
- Full EPAS summary on Badgernet with copy to be sent to the GP.
- Patient should be given instructions on how to register the pregnancy via the Trust website (Issue “Badger Notes – A Woman’s Guide”) or GP, if not already done so.
- This information should still be given even if the woman is planning a termination of pregnancy, as some women will choose not to continue with that option.
- Consider any possible safeguarding issues as appropriate
- Give patient emotional support where required.
- Give contact numbers for further advice/support/referral.
- **If patient unstable or requires medical assessment perform T, P, BP, ward test, FBC, G&S, arrange assessment and admit if appropriate to Gynaecology Ward/GATU.**

NB. If patient >12/40 Anti D to be given as per Anti-D guideline

5.2 Progesterone

- Offer vaginal micronised progesterone (Utrogestan or Cyclogest) 400 mg twice daily to women with an intrauterine pregnancy confirmed by a scan, if they have vaginal bleeding and have previously had a miscarriage.
- There is no evidence that Progesterone is of any benefit where there is no previous history of miscarriage, or for previous ectopic pregnancy.
- For women who have a scan that is of uncertain viability:
 - Prescribe 2 weeks of treatment on a hospital prescription as Utrogestan 400mg (2x200mg vaginal capsules) or Cyclogest vaginal pessaries 400mg twice daily per vagina
 - Arrange follow up scan for viability after at least 7 days (ideally 2 weeks) depending on individual circumstances as per miscarriage guideline
 - If the follow up scan confirms viability, then prescribe a further 2 weeks of treatment and communicate to the GP via letter in appendix 2 or 4
 - If the follow up scan confirms a miscarriage the treatment should be discontinued
- For women who have a scan that shows a confirmed viable intrauterine pregnancy:
 - Prescribe 4 weeks of treatment on a hospital prescription as Utrogestan 400mg (2x200mg vaginal capsules) or Cyclogest vaginal pessaries 400mg twice daily per vagina
 - Communicate to GP via standardised letter (appendix 3 or 5) and via Badgernet
 - Routine follow up scans are not required
 - Ensure pregnancy has been booked as per section 5.1.
- Utrogestan should not be given where the patient has an allergy to peanut or soya

- Utrogestan and Cyclogest should be avoided where the woman is breastfeeding as the progesterone has found to be present in milk
 - At present there is no known effective alternative in this cohort of patients.
- If a Viable pregnancy is confirmed the GP is instructed to continue the Utrogestan or Cyclogest until 16 weeks completed gestation (16+0).
- Progesterone is of no benefit once the diagnostic criteria for a miscarriage have been fulfilled.
- Patients should be advised that use of progesterone will not prevent all miscarriages and is of most benefit if the woman has had three or more miscarriages before.
- Women should be advised that use of pessaries into the vagina has not been associated with causing miscarriage.

5.3 Prescribing information (BNF)

5.3.1 Contraindications

- History of thromboembolism
- Missed miscarriage
- Thrombophlebitis
- Acute porphyrias
- Breast cancer
- Genital cancer
- History during pregnancy of idiopathic jaundice
- History during pregnancy of pemphigoid gestationis
- History during pregnancy of severe pruritus
- For Utrogestan® oral and vaginal capsules, manufacturer advises contra-indicated in patients with hypersensitivity to soy or peanut products—contains soya lecithin.
- Avoid if breast feeding as present in milk

5.3.2 Cautions

- Conditions that may worsen with fluid retention
- Diabetes (progestogens can decrease glucose tolerance—monitor patient closely)
- History of depression
- Migraine
- Risk factors for thromboembolism

5.4 Patient Involvement

- All patients are to be seen by a member of EPAS staff.
- Scan findings should be discussed with the patient.
- Some women will need more information, support and reassurance and this must be recognised and supported accordingly with follow up visits if necessary.
- Adequate time should be given to meet patient needs.

6.0 Training

- 6.1 All staff receive continuous in-house training and receive regular updates from The Association of Early Pregnancy Units
- 6.2 All staff employed by SATH will be informed how to access guidelines on the intranet
- 6.3 Information regarding new and updated guidelines is circulated by email/memo to medical and nursing staff
- 6.4 A paper copy is placed in the Gynaecology Guideline Folder on Ward 14 and file in EPAS with a notice posted to alert staff to be aware of new and updated guidelines

7.0 Monitoring/audit

Compliance with this guideline / SOP will be audited as part of the Shrewsbury and Telford Hospital NHS Trust's five-year rolling programme of NICE and local guideline audits, unless circumstances require an earlier or more frequent audit. The audit will be carried out against the auditable standards and the results of the audit will be reported and acted on in accordance with the Trust Clinical Audit Policy (CG25).

8.0 References

Coomarasamy A et al; Micronized vaginal progesterone to prevent miscarriage: a critical evaluation of randomized evidence. *Am J Obstet Gynecol.* 2020 Aug;223(2):167-176. doi: 10.1016/j.ajog.2019.12.006. Epub 2020 Jan 31. PMID: 32008730; PMCID: PMC7408486.

Harlev A, Levy A, Zaulan Y, Koifman A, Mazor M, Wiznitzer A, Faizayev E, Sheiner E. Idiopathic bleeding during the second half of pregnancy as a risk factor for adverse perinatal outcome. *J Matern Fetal Neonatal Med.* 2008 May;21(5):331-5. doi: 10.1080/14767050802038124. PMID: 18446661.

NICE NG126: Ectopic Pregnancy and Miscarriage: Diagnosis and Management (Nov 2021)

EARLY PREGNANCY BLEEDING & PROGESTERONE

Progesterone is an effective treatment for women who have early pregnancy bleeding AND 1 or more previous miscarriages

20 %
OF WOMEN

Bleeding before 12 weeks can happen for about **20% of pregnant women**.

2 in 3
continue their pregnancy



1 in 3
miscarry

Although women are often worried at the sight of blood, **it is not always a sign of a problem**.

However, bleeding in early pregnancy does increase the risk of miscarriage.

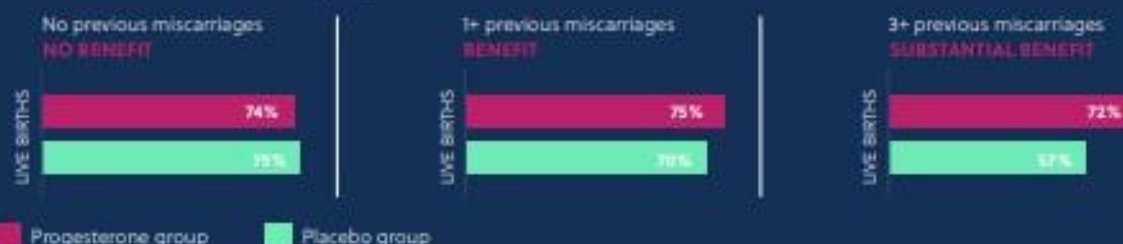


What is progesterone? Progesterone is a natural hormone that is important during pregnancy; it helps to grow the lining of the womb and helps the mother's body to accept the growing baby.



A large UK-wide medical research trial* has now shown that **progesterone can prevent miscarriage** if you are bleeding in early pregnancy AND have a history of previous miscarriage.

Who was shown to benefit from progesterone treatment?



What is the treatment?

Progesterone (the drug used in the trial was called Utrogestan®) is taken as vaginal pessaries, 400mg twice daily, from the time you see a doctor with bleeding up to 16 weeks of pregnancy.

400mg
2xDAILY

Progesterone treatment is safe to use in pregnancy.



WHERE CAN I GET THIS TREATMENT?

If you are bleeding in early pregnancy:

- please call your Early Pregnancy Unit (EPU) at your local hospital and ask to be seen
- if your EPU is closed, visit your hospital Accident and Emergency unit
- bring this guidance with you or refer to www.tommys.org/PRISM.

This information was produced by Tommy's with the guidance of Professor Ami Coomarasamy and his team at the Tommy's National Centre for Miscarriage Research. The trial took place from May 2015 - 2017. Follow-up of patients was completed by June 2018. To find out more visit www.tommys.org/PRISM.

*PRISM Trial: Multi-centre randomised placebo-controlled trial of effects of vaginal progesterone in women with early pregnancy bleeding. Coomarasamy et al. (2019). A Randomized Trial of Progesterone in Women with Early Pregnancy Bleeding. *N Engl J Med*, May 2019.

This study was funded by the National Institute for Health Research (NIHR) HTA programme (project reference 12/16726). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Tommy's is a registered charity in England and Wales (1060508) and Scotland (SC039280).

Tommy's

GP

**Shropshire Women's & Children's Centre
Princess Royal Hospital**

Apley Castle
Telford
TF1 6TF

Early Pregnancy Assessment Unit (EPAS)

Tel: 01952 641222
Ext: 5944
Ext: 1204

Ref:

12 May 2023

Dear Dr

Re:

Date of Birth:

NHS No:

Address:

Prescribing information for Micronised Progesterone (Utrogestan®) in threatened miscarriage

Your patient has been seen in the Early Pregnancy Assessment Service (EPAS) with vaginal bleeding in pregnancy and has been commenced on micronized progesterone (Utrogestan) 400mg (2X200mg vaginal capsules) twice daily per vagina as recommended by NICE (NG126).

Ultrasound scan today shows an intra uterine pregnancy of uncertain viability. 2 weeks supply has been prescribed, we will then rescan to confirm viability. If the pregnancy is ongoing a further 2 weeks supply will be prescribed as per guidance. Can you then please continue until 16/40 gestation, as agreed by the Area Prescribing Committee.

Verbal and Written Information has been given to the patient re benefits and risks. The patient has advised us she is not allergic to peanuts or Soya milk. Your patient continues to have open access to EPAS and has been advised to contact for further monitoring if she has any concerns or further fresh vaginal bleeding.

Please note Utrogestan is not licensed for this purpose. The unlicensed use of Utrogestan for prevention of miscarriage is recommended by the NICE guidelines (ectopic pregnancy of miscarriage: diagnosis and initial management NICE guideline NG126)

Yours sincerely

Early Pregnancy Assessment Service

GP

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Ultrasound scan today shows a viable intrauterine pregnancy (IUP) at weeks gestation. 4 weeks supply has been prescribed as per guidance. Can you then please continue until 16/40 gestation, as agreed by the Area Prescribing Committee.

Verbal and Written Information has been given to the patient re benefits and risks. The patient has advised us she is not allergic to peanuts or soya milk. Your patient continues to have open access to EPAS and has been advised to contact ourselves for further monitoring if she has any concerns or further vaginal bleeding.

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Yours sincerely

GP address

Early Pregnancy Assessment Unit (EPAS)
Tel: 01952 641222
Ext: 5944 or 1204

07 March 2024

Dear Dr

Re:

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NHS No:

Address:

Prescribing information for Micronised Progesterone (Cyclogest®) in threatened miscarriage

Your patient has been seen in the Early Pregnancy Assessment Service (EPAS) with vaginal bleeding in pregnancy and has been commenced on Cyclogest vaginal pessaries 400mg twice daily per vagina as recommended by NICE (NG126).

Ultrasound scan today shows an intra uterine pregnancy of uncertain viability. 2 weeks supply has been prescribed; we will then rescan to confirm viability. If the pregnancy is ongoing a further 2 weeks supply will be prescribed as per guidance. Can you then please continue until 16/40 gestation, as agreed by the Area Prescribing Committee.

Verbal and Written Information has been given to the patient re benefits and risks. The patient has advised us she is not breast feeding. Your patient continues to have open access to EPAS and has been advised to contact for further monitoring if she has any concerns or further fresh vaginal bleeding.

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Yours sincerely

Early Pregnancy Assessment Service

Copies:

PRIVATE & CONFIDENTIAL

FOR ADDRESSEE ONLY - Patient

Appendix 5: Viable Cyclogest Template

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Princess Royal Hospital**

GP

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Threatened Miscarriage: Management

1.0 Process

1.1 Management

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- Create MIS episode.
- Perform Ultrasound scan.
- Discuss scan findings.
- Take full clinical history including past obstetric history
- Give health education advice eg. Folic acid, smoking, diet, alcohol, general health, pain and bleeding (with relevant information leaflets) to all women
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 - For women with recurrent bleeding, a speculum examination should be performed, if not already done so to look for local causes
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- Give contact numbers for further advice/support/referral.
- If patient unstable or requires medical assessment perform T, P, BP, ward test, FBC, G&S, arrange assessment and admit if appropriate to Gynaecology Ward/GATU
- If patient > 12/40 Anti D to be given as per Anti D Guideline

1.2 Progesterone Prescribing

- Offer vaginal micronised progesterone 400 mg twice daily to women with an intrauterine pregnancy confirmed by a scan (see 5.2), if they have vaginal bleeding and have previously had a miscarriage.
 - For women who have a scan that is of uncertain viability:
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 - ❖ Arrange follow up scan for viability after at least 7 days (ideally 2 weeks) depending on individual circumstances
 - ❖ If the follow up scan confirms viability then prescribe a further 2 weeks of treatment and communicate to the GP via letter
 - ❖ If the follow up scan confirms a miscarriage the treatment should be discontinued
 - For women who have a scan that shows a confirmed viable intrauterine pregnancy:
 - ❖ Prescribe 4 weeks of treatment on a hospital prescription as Utrogestan 400mg (2x200mg vaginal capsules) or Cyclogest 400mg twice daily per vagina
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