



Title	Medical Management of Ectopic Pregnancy
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Healthcare Inequality Impact Assessed <small>(statutory for policies)</small>	N/R



Medical Management of Ectopic Pregnancy

Treatment Pack

Clinical details	
Patient name:	
CHI:	
DOB:	
Address:	

Responsible clinicians (Please print name, signature and initials)			
Name	Role	Signature	Initials

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- Part 1 Criteria for Medical Management
- Part 2 Consent form for Methotrexate
- Part 3 Methotrexate prescription
- Part 4 Follow up

Part 1

Criteria for Methotrexate

All cases must be discussed with the on-call consultant

Is this patient suitable for Methotrexate? Review the diagnosis, patient characteristics, clinical features, ultrasound findings, serum HCG concentration, medical history and current medication use.

1. Diagnosis of ectopic pregnancy

This is made from a combination of clinical features, USS findings and serum HCG assessments.

The following may support a diagnosis:

- Ectopic pregnancy seen on USS
- An empty uterus with a suboptimal rise in hCG (<66% over 48h)
- An empty uterus with an adnexal mass or free fluid
- An empty uterus with no chorionic villi seen on endometrial sampling

A viable intrauterine pregnancy should have been excluded

Is a diagnosis of ectopic pregnancy likely?	Yes	No
Name and signature of clinician		

2. Patient characteristics

Any of the following would usually exclude a patient from treatment with Methotrexate:

- Patient would prefer conservative or surgical management
- Patient is unable or unwilling to attend at least 6 weeks follow up
- Patient is unable or unwilling to abstain from alcohol for 7 days
- Patient is currently breast feeding and cannot stop

Is the patient suitable?	Yes	No
Name and signature of clinician		

3. Clinical features

Any of the following would usually exclude a patient from treatment with Methotrexate:

- Haemodynamic instability
- Severe abdominal pain
- Peritonism (NICE 2012)

Is the patient suitable?	Yes	No
Name and signature of clinician		

4. USS findings

The scan should be within 24h or within 1 day of the first treatment if there has been clinical change. Any of the following would usually exclude a patient from medical management of ectopic pregnancy:

- Fetal heart seen or clear yolk sac seen in adnexa
- An adnexal mass >3.5cm
- Moderate or significant free fluid (NICE 2012)

Is the patient suitable?	Yes	No
Name and signature of clinician		

5. Serum HCG levels

A further sample should be taken on the day of treatment.

A serum HCG >5000 would usually exclude a patient from medical management of Methotrexate (NICE 2012)

A lower serum HCG (ideally <1500) is associated with a higher chance of success (NICE 2012)

Is the patient suitable?	Yes	No
Name and signature of clinician		

6. Medical History

The following conditions would exclude the use of Methotrexate:

- Active peptic ulcer disease
- Renal disease
- Hepatic disease
- Severe anaemia
- Other severe medical illness

Is the patient suitable?	Yes	No
Name and signature of clinician		

7. Medication history

Review all current medication use. The following drugs are contraindicated with Methotrexate:

NSAIDS, aspirin, penicillins, sulphonamides, trimthoprim, tetracylines, diuretics, phenytoin, antimalarials, cyclsprin, retinoids, probenecid, folic acid, hypoglycaemics, live vaccines, nephrotoxic and hepatotoxic drugs

Is the patient suitable?	Yes	No
Name and signature of clinician		

Overall Suitability

Based on all the above, is the patient suitable for medical management with Methotrexate?	Yes	No
Name and signature of clinician		

In exceptional circumstances, Methotrexate may be used when these criteria are not. Please document details here:

The following guidelines have been used:

NICE 2012, RCOG green top guideline 21 2016

Part 2 Consent form *Patient Copy*

Patient information Sheet

This sheet contains important information on the use of Methotrexate for the management of ectopic pregnancy. Methotrexate is a drug that has been used in high repeated doses to treat some tumours and autoimmune conditions. A single, or sometimes double dose, of Methotrexate has been shown to be an effective non-surgical alternative treatment of ectopic pregnancy. This is a non-licensed use of the drug but it has been used for this purpose in many hospitals in the UK and around the world for many years and has been found to be safe and effective. It is effective in about 90% cases and can reduce the need to have surgery. Its use has been agreed by the Royal college of Obstetricians and Gynaecologists and by NICE.

To make sure you are happy with this treatment you should go over each point and discuss them with a nurse or doctor. You will be given a copy to take away and keep. Please tick each point to say that you understand it.

1. Although treatment with Methotrexate for ectopic pregnancy has been tested, recommended and is widely used, the drug company making it does not include it in the list of conditions it was designed to treat (it is an <i>unlicensed use</i> .)	
2. Three quarters of women will get some discomfort or pain following treatment. This is usually 3 to 7 days after treatment and lasts 4-12 hours and is likely due to the pregnancy resolving.	
3. Significant side effects are unusual. The commonest side effects are bloating, gas and colicky abdominal pain.	
4. Rare side effects include a sore mouth, lips and eyes, nausea, fatigue and diarrhoea.	
5. Severe side effects are very rare. They include problems with the liver and blood. For this reason it is important that you attend for follow up for blood tests.	
6. Until treatment is complete there is a small chance that the ectopic pregnancy can cause problems or rupture. Although unlikely it is important to report any concerns such as pain or feeling unwell and keep emergency contact details available. Overall, less than 1 in 10 women will require emergency surgery after medical treatment with Methotrexate.	
7. Until treatment is complete there is a small chance that the ectopic pregnancy can cause problems or rupture. Although unlikely it is important to report any concerns such as pain or feeling unwell and keep emergency contact details available. Overall, less than 1 in 10 women will require emergency surgery after medical treatment with Methotrexate.	
8. Sometimes a second (or rarely third) dose of methotrexate may be required. This is the case in about 1 in 8 women.	
9. A pregnancy in the future is unlikely to be an ectopic. The chances of a future ectopic is less than 1 in 10. However the chance is increased compared to the general population and we suggest getting in touch to arrange an early scan in future pregnancies.	

In order to make the treatment with Methotrexate as safe as possible, it is important that you are able to attend for follow up and during this time we ask you to follow some advice. Please make sure you are happy with the following and tick each point to say you understand.

1. Although allergic reactions are rare I agree to stay in the department for 1 hour after the injection to confirm I am okay.	
2. I agree to return to hospital for all the necessary blood tests. This is usually twice a week for the first two weeks and then once a week until the pregnancy test is negative. This may involve attending for more than 6 weeks.	
3. This means I should stay in the Borders general hospital area until discharged from follow up.	
4. I agree to not have any alcohol for 1 week following the injection.	
5. As the skin can burn more easily with this treatment I agree to avoid sunbeds and sunlight during this time.	
6. As Methotrexate works by blocking folic acid I should stop taking my folic acid or other vitamin preparations that include folic acid.	
7. I agree to avoid sexual intercourse during follow up or until I am told that it is safe.	
8. As Methotrexate can cause serious harm to an early pregnancy, I agree to not become pregnant for the next 3 months until the Methotrexate is safely out of my system.	
9. I am aware that the side effects may be worse if I am dehydrated and I should have a good fluid intake during follow up.	
10. I agree to get in touch if I'm concerned about symptoms or side effects or have further questions.	

I have gone over the above checklists and have been given the opportunity to discuss these with a member of staff and ask any questions.

Patient's name	Patient's signature	Date

I have gone through the above checklists and have answered any questions that the patient may have

Clinician's name and designation	Clinician's signature	Date

Emergency contact details

Pregnancy assessment unit (Mon-Fri 0840 – 1630): 01896 826735
Outside these hours please phone: 111 (NHS 111)

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Patient's name	Patient's signature	Date

I have gone through the above checklists and have answered any questions that the patient may have

Clinician's name and designation	Clinician's signature	Date

Methotrexate Prescription

Notes on prescribing

Methotrexate is prescribed for the 'medical management of ectopic pregnancy' at a dose of *50mg/m²* by intramuscular injection. The product used to prepare this dose is Methotrexate *50mg/2ml*. Usual doses are in range of 75 - 100mg (Body Surface Area of 1.5 to 2.0), which corresponds to dose volumes of 3.0 to 4.0ml. Usual practice is to divide the dose equally between two syringes, so the patient receives two injections at different sites.

The dose is prepared in the BGH Pharmacy Aseptic Unit. This service is only available MON-FRI, with requests received only from 9am until 4pm. Once the need for this treatment is identified, please contact the Aseptic Unit on 26617 or Clinical Pharmacist on 26602 for advance warning and when dose is required. If the need for this treatment is identified out of hours, the product can only be prepared at the next scheduled opening of the Aseptic Unit.

Prior to prescription

The following blood tests need to be taken:

- HCG (on day of Methotrexate)
- FBC , U+Es and LFTs (within 48h)
- G+S (within 5 days)

In addition, current height and weight need to be known and recorded on the front of the drug kardex. If any results are abnormal please discuss with on-call registrar.

	Date	Result
HCG		
FBC		
Hb		
WCC		
Plt		
U+Es		
Urea		
Na		
K+		
Creatinine		
LFTs		
Bilirubin		
ALT		
Alk phos		
Albumin		

Height	
Weight	

Calculating dose

Step 1

Calculate BSA (body surface area).

$$BSA (m^2) = \sqrt{\left(\frac{weight (kg) \times height (cm)}{3600}\right)}$$

Round to the nearest 2 decimal places

BSA (M ²)	
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Step 2

$$Dose (mg) = 50mg \times BSA (m^2)$$

Methotrexate Dose (mg)	
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This dose should be written on the kardex as a once only prescription. It is an IM medication.

Methotrexate administration

Check that prescription form is filled in and signed correctly. 2 practitioners are required for the injection. The details on the pre-prepared syringe should be checked and compared with this prescription. Patient identify should be confirmed. Wash hands and put on gloves and apron, Give by deep IM injection (not more than 4ml per injection.) Dispose of the syringe and needle in cytotoxic sharps bin. Dispose of apron and gloves in clinic waste bin and wash hands. In case spillage wash off skin and contact pharmacy for advice.

Following Methotrexate administration

The patient should be observed for 1 hour in the department following injection.

Anti D is required in all resus negative women.

Patients should be advised to expect some abdominal pain as the pregnancy resolves and this can be managed with paracetamol. If the pain is not helped by this, is severe, the patient feels dizzy or has shoulder tip pain or heavy bleeding they should seek help. Other symptoms to report include breathing difficulties, nose bleeds or fever or other unexpected symptoms. New medications should be avoided over the next 7 days. Other household members should be advised to avoid exposure to bodily fluids over the next 7 days.

Follow up should be arranged for D4 (Administration is D1)

Methotrexate follow up

D1 is the day of Methotrexate administration

D4 Measure Serum HCG, FBC, U+Es and LFTs

D7 Measure Serum HCG

Calculate drop from D4 to D7. If it is less than 15%, a second dose of Methotrexate may be required (must be authorised by a consultant.) If is greater or equal to 15% plan to repeat HCG on D11.

D11 Measure serum HCG, FBC, U+Es and LFTs

Calculate drop in serum HCG from D7 to D11. If it is less than 15%, a further dose of Methotrexate might be required (must be authorised by a consultant.) If it is greater than or equal to 15% plan to repeat HCG on D18.

D18 Measure serum HCG

Weekly HCGs should then be taken until serum HCG <20

Following subsequent doses of Methotrexate, monitoring begins again from D1.

Methotrexate monitoring form

Patient name	
Date of Birth	
CHI number	
Address	

Contact number	
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Serum HCGs			
Prior to Methotrexate			
Date	HCG concentration		
Decision for Methotrexate			
Day	Date	HCG concentration	
1 (date of Methotrexate)			
4			
7			
Calculate percentage fall from D4 to 7 . If <15% another dose may be required. Percentage fall =			
11			
Calculate percentage fall from D7 TO D11, If <15% another dose may be required. Percentage fall =			
18			
25			
32			
39			
46			
	Pre-Methotrexate	D4	D11
FBC			
Hb			
WCC			
Plt			
U+Es			
Urea			
Na			
K+			
Creatinine			
LFTs			
Bilirubin			
ALT			
Alk phos			
Albumin			