University Hospitals of Derby and Burton NHS Foundation Trust

PROTOCOL

Administration of Ferric Subsulphate (Monsel's) solution By Clinical Nurse Specialist in colposcopy/hysteroscopy clinic at Royal Derby Hospital

Documentation details

Reference no:	UHDB158
Version no:	V1
Valid from:	11/05/2022
Review date:	11/11/2024
Expiry date:	10/05/2025

Change history

Version number	Change details	Date
V1	New template	23/3/22

Glossary

Abbreviation	Definition

1. Protocol template development (Protocol Working Group)

Protocol Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who will work under a Protocol (or manages the staff who do). If this is a review of existing Protocol, replace previous names with the individuals involved for this version

Name	Designation
Mr O Tamizian	Lead Colposcopist
Miss S Kolhe	Lead Hysteroscopist
Mrs G Lowe	Lead Nurse Colposcopist
Mr D Casayuran	Nurse Hysteroscopist
S Dumbleton	Women and Children's Lead Pharmacist

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
N/A		

2. Organisational authorisations

The Protocol is not valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this Protocol for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Colposcopy and Hysteroscopy Department within Gynaecology Outpatients department at Royal Derby Hospital
Limitations to authorisation
The professionals to whom this protocol applies are the clinical nurse specialist(s) in colposcopy.
Agreed rationale for protocol use in place of a PGD (Patient Group Direction)
To define a framework for staff who administer unlicensed medication after a patient specific direction (from a prescriber) has been received to authorise use of the unlicensed medicine. Patients are referred to the colposcopy clinic by registered medical professionals with the expectation and understanding unlicensed agents will be used and that they are authorising this use. As a Patient Group Direction cannot cover the administration of ferric subsulphate (Monsel's) solution (unlicensed product), this protocol has been drawn up locally by doctors, pharmacists and other appropriate professionals.

Organisational Authorisation			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)	James Hooley	**Signed copy held in Pharmacy**	**11/05/2022**

Additional signatories			
Role	**Name**	**Sign**	**Date**
Women and Childrens Lead Pharmacist	Susi Dumbleton	**Signed copy held in Pharmacy**	**29/03/2022**
Lead Colposcopist	Onnig Tamizian	**Signed copy held in Pharmacy**	**24/03/2022**
Lead Hysteroscopist	Shilpa Kolhe	**Signed copy held in Pharmacy**	**03/05/2022**
Clinical nurse Specialist in colposcopy	Gaynor Lowe	**Signed copy held in Pharmacy**	**25/03/2022**
Clinical nurse Specialist in hysteroscopy	Dennis Casayuran	**Signed copy held in Pharmacy**	**24/03/2022**

Local enquiries regarding the use of this PROTOCOL may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a healthcare worker authorisation sheet. Individual healthcare workers must be authorised by name to work to this PROTOCOL.

3. Characteristics of staff

Qualifications and professional registration	Registered nurse with a current NMC registration
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Completion of Medicines Management Drug Assessment - Individual has read and understood full content of this Protocol and signed authorisation (section 7) - Trained according to the British Society of Colposcopy and Cervical Pathology guidelines or has completed nurse hysteroscopist training - Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the protocol.
Competency assessment	Approved drug assessment Individuals operating under this Protocol are personally responsible for ensuring they remain up to date with the use of all medicines included in the Protocol - if any training needs are identified these should be discussed with the either authorising manager (section 7) or the manager within the Protocol working group (section 1) so that further training can be provided as required.
Ongoing training and competency	Annual Medicines Safety Training (essential to role) Review/repeat initial training above when this protocol is revised It is the responsibility of the individual registered nurse to remain updated, with evidence of continued professional development in relation to colposcopy services including annual mandatory training in CPR/life support/anaphylaxis competences, with evidence of updates as required.
The decision to administer or supply any medication rests with the individual healthcare worker operating under this protocol who must abide by the protocol and any associated organisation policies.	

4. Clinical condition or situation to which this Protocol applies

Clinical condition or situation to which this Protocol applies	Used during a colposcopy or hysteroscopy. It is applied to the cervix post cervical biopsy to stem bleeding, if bleeding occurs. Interference with histopathological tests may occur and so apply after completion of biopsies only.
Criteria for inclusion	Patients over 16 years requiring a colposcopy, cervical biopsy and hysteroscopy
Criteria for exclusion	• Previous sensitivity or intolerance to Ferric Subsulphate • Patients under 16 years • Pregnant women
Cautions including any relevant action to be taken	None applicable
Action to be taken if the patient is excluded	• Refer to medical staff for review and prescribing of alternative agent if appropriate. • Record reasons for exclusion in patient notes • Advise patient on alternative treatment
Action to be taken if the patient or carer declines treatment	Document refusal, action taken and advice given in nursing documentation and refer to medical staff if appropriate.
Arrangements for referral for medical advice	Colposcopy and Hysteroscopy clinics are undertaken under consultant lead and the nurse specialist may contact them directly for support.

5. Description of treatment

Name, strength & formulation of drug	Ferric Subsulphate Solution (Monsel's solution)
Legal category	Unlicensed Product
Route / method of administration	Topical
Indicate any unlicensed or off-label use (if relevant)	Best practice advice given by BSCCP is used for this protocol and may vary from the manufacturer's summary of product characteristics. See UHDB TRUST POLICY FOR THE USE OF UNLICENSED MEDICINES
Dose and frequency of administration	As required, applied using cotton tipped applicator
Duration of treatment	Throughout duration of procedure
Quantity to be supplied (leave blank if protocol is administration ONLY)	Not applicable
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Store in a locked medicines cupboard.

Drug interactions	There are no known drug interactions for ferric subsulphate (Monsel's) solution.
Identification & management of adverse reactions	Irritation at site of application may occur.
Management of and reporting procedure for adverse reactions	• Consult medical advice if an adverse event occurs • Healthcare workers and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	Not applicable
Patient advice / follow up treatment	Monitor for sensitivity reactions; Verbal advice on why drug administered, action of the drug and subsequent management of condition The individual/carer should be advised to seek medical advice in the event of an adverse reaction.
Records	The authorised healthcare practitioner must sign (print) in the appropriate records. State 'administered under a protocol' with name and signature of authorised practitioner. For EPMA: Document the utilisation of the medicine under Protocol by ordering the appropriate drug order item against the correct patient record in EPMA. Either the system holding the record, or the healthcare practitioner working under the Protocol, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered via Protocol Records should be signed and dated (or a password controlled e-records).

	All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this Protocol should also be in the clinical area for audit purposes

6. Key references

Key references	• *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2* • Colposcopy – a Practical Guide: M Shaffi & S Nazeer, 2006. • *British Society for Colposcopy and Cervical Pathology; Colposcopy Practice Statement, 2017, https://www.bsccp.org.uk/assets/file/uploads/resources/BSCCP_Local_Anaesthetic_Statement_09.05.17.pdf, accessed 25/01/22*

7. Registered health professional authorisation sheet

Protocol [version]: Colposcopy/Hysteroscopy Gynae Outpatient – Ferric Subsulphate (Monsel's) [v1]
Protocol ref: UHDB158
Valid from: 11/05/2022 **Expiry date: 10/05/2025**

Before signing, check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that
a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this protocol.

The decision to administer or supply any medication rests with the individual healthcare worker operating under this protocol who must abide by the protocol and any associated organisation policies.

I confirm that I have read and understood the content of this Protocol and that I am willing and competent to work to it.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

I confirm that those named above have declared themselves suitably trained and competent to work under this Protocol. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named healthcare workers who have signed the Protocol to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of healthcare workers to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the Protocol is in-use to serve as a record of those authorised to work under this Protocol.