University Hospitals of Derby and Burton
NHS Foundation Trust

PROTOCOL

Supply/Administration of Mannitol By Clinical Physiologists in Clinical Measurement at Royal Derby and Queens Hospitals.

Documentation details

Reference no:	UHDB296
Version no:	1.0
Valid from:	25/04/2024
Review date:	25/10/2026
Expiry date:	24/04/2027

Change history

Version number	Change details	Date
1	New UHDB format	16/02/2024

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
Claire Pitcher	Principal Clinical Physiologist
James Kerr	Senior Clinical Pharmacist
Priya Daniel	Respiratory Consultant - Clinical Lead

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	n/a	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
Clinical measurement Services UHDB
Limitations to authorisation
These protocols are to be used by Clinical Physiologists who cannot carry out administration of medicines under group directions, and therefore have to administer using the protocols. The drug should be requested via the referral form identifying that the attending patient requires medication as part of the test. Method of delivery, dose and frequency should be indicated. The authorised signatory should be a medical prescriber, or Doctor.
Agreed rationale for protocol use in place of a PGD (Patient Group Direction)
- *This provides a framework for staff who are not legally permitted to operate under PGDs to do so after a patient specific direction (from a prescriber) has been received to authorise use of a prescription medicine.*

Organisational Authorisation			
Role	**Name**	**Sign**	**Date**
James Hooley *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	Medicines Safety Officer	**Signed copy held in Pharmacy**	**25/04/2024**

Additional signatories			
Role	**Name**	**Sign**	**Date**
Divisional Pharmacist *Clinical Pharmacist from Protocol working group*	James Kerr	**Signed copy held in Pharmacy**	**19/03/2024**
Respiratory Consultant *Doctor*	Priya Daniel	**Signed copy held in Pharmacy**	22/04/2024
Principal Clinical Physiologist *Registered Professional representing users of the PROTOCOL*	Claire Pitcher	**Signed copy held in Pharmacy**	**19/02/2024**

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	Clinical Physiologists/Practitioners band 5 and above who have qualified and passed BSC Hons in Clinical Physiology or equivalent experience.
Initial training	- Completion of Medicines Management Drug Assessment - Individual has read and understood full content of this Protocol and signed authorisation (section 7) - Training and competency in Mannitol Challenge testing
Competency assessment	Staff will gain competency as part of their degree requirements and will be signed off by qualified staff. Competency assessment performing Mannitol challenge tests. 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 BLS with AED (defibrillator) training and competency. Mandatory H&S training Annual appraisal.
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	To be used in challenge testing procedure to assess bronchial hyper responsiveness by performing spirometry following attached protocol
Criteria for inclusion	Patients over 18 years with suspected asthma.
Criteria for exclusion	Known hypersensitivity to Mannitol or any capsule ingredients. Severe airflow limitation i.e. FEV1<50% predicted FEV1 or FEV1 < 1 litre Conditions that could be compromised by induced bronchospasm or repeated blowing manoeuvres. These include Aortic or Cerebral aneurysm, uncontrolled hypertension, myocardial infarction or a cerebral vascular accident in the last 6 months.
Cautions including any relevant action to be taken	Ensure bronchodilators are available and staff are available who are authorised to administer them if required. Ventilatory impairment (baseline FEV1 of less than 70% of predicted normal values or an absolute value of 1.5 l or less in adults), spirometry induced bronchoconstriction, haemoptysis of unknown origin, pneumothorax, recent abdominal or thoracic surgery, recent intraocular surgery, unstable angina, inability to perform spirometry of acceptable quality or upper or lower respiratory tract infection in the previous 2 weeks
Action to be taken if the patient is excluded	Refer back to medical staff. Document reason for exclusion
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 Advise patient on alternative treatment
Arrangements for referral for medical advice	Monday to Friday 08:30am – 5pm: Clinical Measurements Department, RDH Outside these hours: Patients should contact their GP

5. Description of treatment

Name, strength & formulation of drug	Mannitol (Osmohale) capsules containing powder for inhalation. Capsules may contain 0 mg, 5 mg, 10 mg, 20 mg or 40 mg mannitol
Legal category	POM
Route / method of administration	Via an inhaler
Indicate any unlicensed or off-label use (if relevant)	N/A Drug licensed for challenge testing Drug used for treatment of pain relief in muscles.

<table>
<tr><td></td><td>Used for warming the earlobe during collection of capillary blood gas samples.

Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.

For an unlicensed medication – include reference to trust policy including documentation and consent process for unlicensed medicines which must still be applied and outlined in this document.</td></tr>
<tr><td>Dose and frequency of administration</td><td>Patients are given increasing doses of mannitol to assess bronchial hyper responsiveness which is monitored by measuring FEV1 during spirometry.

<table>
<tr><td>Dose Step</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr>
<tr><td>Dose</td><td>0mg</td><td>5mg</td><td>10mg</td><td>20mg</td><td>40mg</td></tr>
<tr><td>Quantity</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td></tr>
</table>

<table>
<tr><td>Dose Step</td><td>6</td><td>7</td><td>8</td><td>9</td><td>-</td></tr>
<tr><td>Dose</td><td>80mg</td><td>160mg</td><td>160mg</td><td>160mg</td><td>-</td></tr>
<tr><td>Quantity</td><td>2x40mg</td><td>4x40mg</td><td>4x40mg</td><td>4x40mg</td><td>-</td></tr>
</table>

Maximum dosage determined by FEV1 reduction . Challenge test would be halted when either of the following occurs:
1. >15% fall in FEV1 from baseline (using the highest post 0mg FEV1 as comparator)
2. >10% incremental fall in FEV1 between consecutive OsmohaleTM doses</td></tr>
<tr><td>Duration of treatment</td><td>20-30 minutes
The titration is continued until the patient has a positive response or a total of 635 mg has been administered.</td></tr>
<tr><td>Quantity to be supplied (leave blank if protocol is administration ONLY)</td><td>N/A</td></tr>
<tr><td>Storage</td><td>Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below:

Do not store above 25°C.</td></tr>
<tr><td>Drug interactions</td><td>If the patient is receiving any concomitant medication or treatment it is the responsibility of the person identified in “Staff Group” to ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt advice should be sought and recorded before the drug is administered

A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website:</td></tr>
</table>

	www.medicines.org.uk
Identification & management of adverse reactions	This is not an exhaustive list – for full details see product insert A detailed list of adverse reactions is available in the SPC. Cough during the challenge, Pharyngolaryngeal pain (occurrence may be reduced if the mouth is rinsed after the test) Additional equipment : Saturation monitor, stethoscope, sphygmomanometer. Adrenaline and salbutamol . Consult medical advice if an adverse event occurs. Document in the patient's notes. **Administer bronchodilator if bronchoconstriction occurs as per seperate protocol.** **Seek urgent medical advice if bronchoconstriction is not resolved** This is not an exhaustive list – for full details see summary of product characteristics which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• **Consult medical advice if an adverse event occurs. Document in the patient's notes. Administer bronchodilator if bronchoconstriction occurs** **Seek urgent medical advice if bronchoconstriction is not resolved** • 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	Appointment letter and information leaflet Monitor for sensitivity reactions; verbal advice on why drug administered, action of the drug and subsequent management of condition.
Patient advice / follow up treatment	Patients stay for 30 minutes after procedure. Bronchodilators given if appropriate. Temporary skin reactions such as severe burning sensation, blistering and skin rashes. Patients may feel discomfort if skin sensitive. This is not an exhaustive list – for full details see product insert

Records	The authorised healthcare practitioner must sign (print) name in the appropriate records. State 'administered under a protocol' with name and signature of authorised practitioner. **This would either be documented in the Cardiobase records or on the associated test documentation.** 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	• *Electronic Medicines Compendium http://www.medicines.org.uk/* • *Electronic BNF https://bnf.nice.org.uk/*

7. Registered health professional authorisation sheet

Protocol [version]: UHDB - Clinical Measurements Department - Mannitol [v1.0]
Protocol ref: UHDB296

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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.