NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Intrathecal Phenol 5% in Glycerol in Adults in Neuro Rehabilitation Unit (NRU)

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Approval Group:	Institute of Neurological Sciences Medical Clinical Governance Group

Important Note:

The online version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Protocol for use of intrathecal Phenol 5% in glycerol in adults in Neuro Rehabilitation Unit (NRU)

Intrathecal administration is an extremely high-risk procedure. This policy must be adhered to at all times

Indications

Intrathecal Phenol 5% in glycerol is used in appropriately selected patients for the management of severe spasticity and associated pain in their lower limbs. No other strengths or preparations of Phenol are currently approved for use for this indication.

Eligibility

All patients are vetted for their suitability by a consultant or nominated deputy with the relevant experience, named on the NHS Greater Glasgow & Clyde (NHSGGC) non-cytotoxic intrathecal and intraventricular injections register (NCIII Register), for the appropriateness of patient and treatment selection in accordance with the board policy. Patient (or PoA/Guardian where appropriate) consent must be obtained.

Inclusion criteria

1. Severe lower limb spasticity affecting comfort, function and/or care.
2. Oral medication has been tried without therapeutic effect at maximum tolerated doses, and/or oral medication unlikely to make an impact. These may include Baclofen, Tizanidine, Dantrolene, Benzodiazepines and Gabapentinoids.
3. Therapy and nursing interventions are no longer able to sustain effective management of the patient's lower limb hypertonia.
4. Other treatment interventions such as Botulinum toxin, Phenol nerve blocks, and/or intrathecal Baclofen considered unsuitable or insufficient to address the patient’s lower limb hypertonia.
5. Bladder and bowel dysfunction evident and effective management strategies in place, or patient willing to consider long-term urethral catheter/bowel regime.
6. Individuals are aware of potential effects on lower limb sensation and sexual function.
7. Individuals and carers are aware of the nature of the treatment and potential side effects and agree with the goals of treatment.

Exclusion criteria

1. Children under 16 years of age.
2. Unable to obtain consent unless covered by an Adult with Incapacity procedure or equivalent.
3. Known hypersensitivity to Phenol.
4. Infection, inflammation, bruising or local tissue damage at proposed injection site.
5. Existing acute febrile illness, associated with systemic involvement.

Assessment and management

Patients will be admitted for an inpatient hospital stay. The consultant who specialises in managing spasticity will assess the patient at intervals during their treatment.

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Pre-treatment evaluation

1. Before considering any treatment for spasticity, there must be an overall assessment of trigger factors. Common causes for triggers for spasticity are urinary retention or infection, severe constipation, skin irritation or breaks, pressure sores or increased sensory stimuli from external causes such as ill-fitting orthotic appliances and catheter-leg bags

2. Intrathecal Phenol should only be considered where other treatments are not suitable or are not effective, especially in the context of regional spasticity.

3. A clear statement of the goals of antispasticity treatment must be documented in the notes. These should be agreed with the patient beforehand unless capacity issues prevent this. In this case, these should be discussed with the patient's PoA/Guardian.

4. Before injection a follow-up plan for appropriate therapy and/or orthotics must be agreed and implemented within 3 weeks of injection. This is normally organised by NRU therapy staff prior to admission.

5. Potential side effects during or immediately post-treatment should be discussed with the patient and or carer/relative before treatment. These include blood pressure fall, causing light headedness or nausea. A headache may occur afterward, but should last no longer than a few days. Longer lasting potential side effects should be discussed such as numbness and weakness in the lower limbs. Options about management of bladder and bowels both in the short and long term following the intrathecal Phenol should be discussed with the patient. The injections can affect sexual function by decreasing sensation in the genital area. However following the injection the reduction in lower limb tone, especially in women, may occasionally result in an improvement of sexual function due to improvement of the positioning of the lower limbs.

6. The registered practitioner administering the intrathecal Phenol in glycerol must explain the nature of the procedure, the route of administration and the drug to be administered to the patient. It must be highlighted that the intrathecal administration of Phenol in glycerol is an unlicensed use and verbal and written information must be provided to the patient and/or care givers about the use of unlicensed medication.

7. Informed written consent must be obtained or adults with incapacity procedure or equivalent should be used.

Prescribing

Intrathecal Phenol is an unlicensed medicine. NHSGGC Board policy must be followed. An unlicensed medicine request must be completed for every patient and submitted in a timely manner to the Lead Clinical Pharmacist. Documentation can be found at: http://www.ggcprescribing.org.uk/non-formulary-information/

The intrathecal Phenol used in the Rehabilitation Medicine Department is intrathecal Phenol 5% in glycerol. The maximum dose in one administration is 5mls. The drug is presented as ampoules of 5ml of Phenol 5% in glycerol. A standard pre-printed prescription form must be used for every dose.

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IT Phenol prescription blank.d

This preparation is different from the aqueous Phenol used in peripheral nerve blocks, and the two should never be confused with each other.

Issue and transportation

The request form will be screened electronically by an approved pharmacist from the neuro-pharmacy team, who is on the NHSGGC NCIII register (neruo.pharmacy@ggc.scot.nhs.uk). This will then be e-mailed to the aseptic unit within the Royal Hospital for Children (RHC) who will prepare and dispense the intrathecal Phenol (rhc.aseptic@ggc.scot.nhs.uk). The doctor must collect the intrathecal Phenol from the RHC aseptic unit immediately prior to the procedure.

Pharmacists at the RHC aseptic unit will only issue the intrathecal Phenol to a named doctor who is trained and registered to administer NCIIIs on the NCIII Register. The pharmacist must check the training status of the doctor with the register held in the pharmacy before releasing the NCIIIs. Pharmacists issuing the NCIIIs and the doctor collecting the NCIIIs must sign the intrathecal Phenol request form. **Storage in clinical areas is not permitted.**

Preparation

Intrathecal Phenol should be prepared by a member of staff named in the intrathecal register or be in training working under the supervision of a member of staff authorised and registered to perform the task involved. Pharmacy will supply an ampoule for drawing up at the bedside immediately prior to injection. The calculations and preparation must be double-checked independently by a second member of staff named on the intrathecal register.

If the intrathecal Phenol is prepared in the clinical area, it must be prepared and administered by the same person and must be clearly identifiable at all stages of preparation and administration.

All intrathecal injections must be administered immediately on receipt. Storage in clinical areas is not permitted. If the intrathecal Phenol is not used, it should be returned to the RHC aseptic unit.

Administration

The administering registered practitioner and checker must also initial the “given by/checked by” section of the intrathecal Phenol request form and HEPMA.

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Scheduling of intrathecal Phenol injections must take into account the availability of trained and registered staff. Should registered staff be unavailable, the procedure must be delayed. If technically difficult then another medical practitioner can position the needle in the intrathecal space but the intrathecal medication must be administered by a doctor registered on the NHSGGC NCIII register to administer.

A consultant or nominated deputy named on the NHSGGC NCIII Register must review the patient before the intrathecal Phenol is administered. This is to ensure that the patient is fit for treatment, the correct tests have been conducted, the correct intrathecal Phenol has been prescribed and received and that arrangements have been clearly made for the intrathecal Phenol to be administered by staff named on the NHSGGC NCIII register.

The registered practitioner administering the intrathecal Phenol must sign the appropriate section of the prescription chart. The prescription chart must be present with the intrathecal Phenol at the time of its administration.

Two members of staff, one of which must be named on the NCIII register i.e. doctor/doctor or doctor/nurse, must always independently double-check the following details of all intrathecals before administration and record the checks on the prescription chart:

- Patient's name, date of birth and CHI number
- The drug name
- The drug dose
- The drug strength (5%)
- The drug volume
- The route of administration (i.e. intrathecal)
- The drug expiry date
- Check that the consent form is signed appropriately

It is recommended that the procedures are carried out in the patient's own bed to avoid patient movement, with meticulous attention to aseptic precautions. The patient is placed on the side to be targeted in a modified lateral position with 30°– 40° of pronation, with the trunk at a 30° angle of elevation and a small area of lower back is made temporarily numb with local anaesthetic. The injection is carried out via an 18 gauge standard spinal needle at level L2/3 or L3/4, aiming to reduce hip spasticity with flexor, adductor, and extensor spasms. Following the injection the patient may need to be repositioned and tilted slightly forward so that the drug reaches the right area in the spine. The patient will need to maintain the position as directed by the injector.

A second dose of intrathecal Phenol may be required depending on initial response, and a minimum period of 24 hours should be observed between repeat intrathecal Phenol injections, although practically, this is usually organised a week apart in the same admission. However, repeat intrathecal Phenol injections are usually organised in a follow-up elective admission.

If the initial lumbar puncture is not successful even with the use of ultrasound guidance, the procedure should be abandoned and follow-up plans discussed with the patient and/or family/carer. These may include alternative management options and/or requesting for procedure to be done under fluoroscopy guidance in a separate elective admission.

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Monitoring

All patients administered intrathecal Phenol preparations will be monitored according to the following protocol.

1. Patient should lie semi-recumbent for 4 hours. The patient should lie on one side for ½ hour before being turned to the other side for a further ½ hour, before allowing to lie on their back to facilitate infiltration of the intrathecal Phenol into nerve roots on both sides.
2. Observe patient for 24 hours for the following:
   - Headache
   - Backache
   - Neurological observations/vital signs ½ hourly x 2, hourly x 2, 4 hourly for the remainder of the first 24 hours. A doctor shall observe the patient at appropriate intervals and for as long as necessary. A full account of the medical observation protocol shall be entered in the notes and communicated orally with the doctor on the ward.
3. Encourage a fluid intake of at least 1.5 litres in 24 hours.
4. Record the procedure in appropriate documents.
5. Establish bowel and skin care regimes over an appropriate period of time agreed among the various disciplines. Communicate details of these regimes with carers and district nurses for continuation in the community.

Management of medication incidents and adverse effects

All medication incidents relating to the use of NCIIIs, which includes medication errors, near-miss events and adverse drug reactions, MUST be reported immediately to the patient's consultant and entered in DATIX. The Designated Speciality Lead(s) must also be informed. Adverse drug reactions should also be reported via the Yellow Card Scheme.

If the medication incident is significant, then the NHSGGC Significant Adverse Event Policy must be followed. All incidents relating to the use of an intrathecal agent, should also be reported to the Leads for the Policy.

Follow up

All patients having intrathecal Phenol treatment will be reviewed in the outpatient clinic within 3-6 months following the intervention and further therapy will be provided as required to ensure that the patients achieve the goals identified on admission. If the outcome is sub-optimal, a further discussion will take place between the clinician, the patient and their carer to discuss further treatment options including a repeat of the intrathecal Phenol.

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APPENDIX 1: INTRATHECAL PHENOL 5% IN GLYCEROL INJECTION CARE PATHWAY

Stage 1: ASSESSMENT

- Phenol is discussed as an option for spasticity management in the person with spasticity (PWS).
- Verbal and written information given to PWS, and/or family/carer.
- Treatment goals agreed between clinician and PWS.
- Patient information leaflets supplied.

YES ↓

Discussion about admission date, waiting times and interim management options where relevant

NO ↓

Discussion about an acceptable management option alternative where relevant

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Stage 2: INPATIENT ADMISSION

- Admit to the ward where a medical assessment is completed and routine bloods taken.
- Doctor and physiotherapist review spasticity, complete further assessments and outcome measures.
- Bladder and bowel management are reviewed to ensure appropriate plans in place.
- Patient is reviewed by consultant and risks and benefits are discussed in detail. Informed consent is obtained from the patient or Adult With Incapacity (AWI) form is completed.

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Stage 3: PHENOL ADMINISTRATON

If the decision is made to proceed, the injection is carried out at level L2/L3 or L3/L4 aiding to target certain muscle groups as per protocol using intrathecal Phenol 5% in glycerol only. Patient monitored as per protocol.

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Stage 4: DISCHARGE/REVIEW

- The spasticity team links with community or ward teams to provide education and ensure patient care is planned appropriately. This may involve the patient having a 24-hour positioning plan, a stretching programme and a supportive seating system review.
- A date for review at the spasticity outpatients' clinic is provided before the patient is discharged.
- A rationalisation plan of patient's current anti-spasticity medications is made prior to discharge.

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APPENDIX 2: REFERENCES

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