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.

Version Number:	1
Does this version include changes to clinical advice:	N/A
Date Approved:	28th October 2022
Date of Next Review:	31st May 2025
Lead Author:	Teng Cheng Khoo
Approval Group:	Regional Services Clinical Governance Group

Important Note:

The Intranet 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.

Lead Author: Dr Teng Cheng Khoo (Consultant in Rehabilitation Medicine)
Approved by: Institute of Neurological Sciences Medical Clinical Governance Group
Last Updated: May 2022
Review date: May 2025
Version 3

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

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. (Appendix 2)

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.

Lead Author: Dr Teng Cheng Khoo (Consultant in Rehabilitation Medicine)
Approved by: Institute of Neurological Sciences Medical Clinical Governance Group
Last Updated: May 2022
Review date: May 2025
Version 3

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

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.

Lead Author: Dr Teng Cheng Khoo (Consultant in Rehabilitation Medicine)
Approved by: Institute of Neurological Sciences Medical Clinical Governance Group
Last Updated: May 2022
Review date: May 2025
Version 3

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

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.

Lead Author: Dr Teng Cheng Khoo (Consultant in Rehabilitation Medicine)
Approved by: Institute of Neurological Sciences Medical Clinical Governance Group
Last Updated: May 2022
Review date: May 2025
Version 3

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

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.

Lead Author: Dr Teng Cheng Khoo (Consultant in Rehabilitation Medicine)
Approved by: Institute of Neurological Sciences Medical Clinical Governance Group
Last Updated: May 2022
Review date: May 2025
Version 3

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

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

↓

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.

↓

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.

↓

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.

Lead Author: Dr Teng Cheng Khoo (Consultant in Rehabilitation Medicine)
Approved by: Institute of Neurological Sciences Medical Clinical Governance Group
Last Updated: May 2022
Review date: May 2025
Version 3

APPENDIX 2: Information for patients about Intrathecal Phenol Injections for Spasticity and Pain

Note that this are the contents of the patient information leaflet but will be printed on a separate handout.

What is intrathecal Phenol injection?

Intrathecal Phenol injection is a type of nerve block which is achieved by the injection of Phenol into the spinal canal for the treatment of spasticity and pain in the lower limbs. This helps to relax the muscles that cause involuntary or uncontrolled scissoring of the hips, flexion and bending of the hips and knees and the accompanying muscular spasms. Applying this treatment will help to improve seating, posture, pain control and application of personal care. As this is an invasive treatment it is carried out as a procedure in hospital, which requires an admission between 1-2 weeks with various observations taken during the procedure to ensure safety of the patient. After the injection of the Phenol the patient is often positioned in such a way to direct the medicine towards the target nerves and that position is maintained for about half an hour, thereafter the patient's position could be altered. It is important that after the procedure and once the clinical effect is realised further assessments take place to insure optimum seating, and optimum care, in light of the changes that happens in the lower limbs. The procedure is carried out by a doctor with expertise in this treatment and with a clearly set clinical protocol, which has been approved by the Clinical Governance Committee of the Directorate on behalf of the Health Board.

Who is it for?

Intrathecal Phenol will only be available to patients who meet the following criteria:

1. Severe lower limb spasticity affecting comfort, function and, or care.
2. Oral medication have been tried without therapeutic effect at tolerated or maximum dose, and/or oral medication unlikely to make an impact.
3. Therapy and nursing interventions are no longer able to sustain effective management.
4. Other treatment options such as botulinum toxin, intrathecal baclofen are not suitable.
5. Bladder and bowel dysfunction is evident and effective management strategies are in place.
6. Individuals are aware of potential effects on lower limb sensation and sexual function.
7. Individuals and carers are aware of nature of treatment potential side effects and agree with the goals of treatment.

Is there any special information that I should know before being given this medicine?

Phenol is not licensed for intrathecal use in this country. Further information on unlicensed medicines can be found in the leaflet “Unlicensed Medicines – What you need you know.” Please ask a member of staff for a copy of this leaflet.

What are the benefits?

The intention is to calm the nerve roots to relieve pain and spasticity. The pain in the treated area should be replaced with numbness.

How likely is it to work?

If we can position the needle and inject the Phenol, it is likely to work. Sometimes you may need a second injection if the effect has been less than expected, or wears off with time.

How long does it last and how might it affect you?

The injection is intended to be **permanent** and **non-reversible** in its effects. About one in five patients may need to have the injection more than once for satisfactory effects.

In the process of calming the nerves, you will experience varying degrees of permanent numbness in the lower limbs. It is difficult to predict the degree of numbness you may have.

Most people find numbness preferable to pain and spasms, but some find it unpleasant.

Stiffness and spasms are replaced by floppy weakness of the lower limbs.

We only offer this treatment to patients who are willing to use a catheter for passing urine and already have a bowel regime of regular suppositories to help their bowel movements. We do not offer the injection to patients with good bladder and bowel control.

A small proportion of patients (usually about 1 in 5) will notice increased skin fragility in the weeks after the injection. This may result in skin breakages in areas exposed to pressure. With appropriate care, virtually all such wounds will heal within weeks to months.

About 1 in 10 may experience long term issues with skin fragility, and may need special measures such as regular turns and restrictions on how long they can sit in a chair.

The injection can be potentially fatal, especially if the patient is in a head down position immediately after the injection. However there has never been a reported death from intrathecal Phenol.

How is it done?

The injection takes place in one of the rehabilitation medicine wards. You will usually be in hospital for 1-2 weeks.

Your doctor will explain the injection to you and your relatives. You will also have the opportunity to ask questions. We will ask you to sign a consent form agreeing to the injection.

In carrying out the procedure you will be positioned on your side with your head and upper body tilted upwards.

Your doctor will mark the bones of the spine and select the injection point. This will be in the midline of your back between 2 vertebrae. We will disinfect the skin and numb the area with a local anaesthetic. Most patients will not experience any significant discomfort. Your doctor will insert a needle through the numbed skin, between the vertebrae and into the fluid that bathes the nerves arising from the spinal cord.

Once the needle is in place the injection of Phenol will be painless, but you may feel a warm sensation spreading through the treated area and into the lower limbs. As soon as the injection is completed and we remove the needle we will reposition you (move you into another position). This is to control the spread of the Phenol while it is working. You will remain in bed for the rest of the day and the night.

Will further treatment be needed?

Following the injection, you may need muscle stretches carried out by the physiotherapist, and monitoring by nursing staff in relation to skin integrity and bowel and bladder functioning.

When you go home, you will have a follow up appointment at the out-patient clinic and this will be discussed with you before you are discharged.

Lead Author: Dr Teng Cheng Khoo (Consultant in Rehabilitation Medicine)
Approved by: Institute of Neurological Sciences Medical Clinical Governance Group
Last Updated: May 2022
Review date: May 2025
Version 3

APPENDIX 3: REFERENCES

Intrathecal Phenol to relieve spasticity in paraplegia.
Nathan PW.
Lancet. 1959 Dec 19;2(7112):1099-102.

Intrathecal Phenol in the treatment of reflex spasms and spasticity.
Kelly RE, Gautier-Smith PC.
Lancet. 1959 Dec 19;2(7112):1102-5.

Intrathecal Phenol in the treatment of spasticity.
Pedersen E, Juul-Jensen P.
Acta Neurol Scand Suppl. 1962;38(3):69-77.

Phenol block for control of hip flexor and adductor spasticity.
Awad EA.
Arch Phys Med Rehabil 1972;53:554–7.

The use of intrathecal Phenol for muscle spasms in multiple sclerosis. A description of two cases.
Browne RA, Catton DV.
Can Anaesth Soc J 1975; 22:208–18.

Managing severe lower limb spasticity in multiple sclerosis: does intrathecal Phenol have a role?
Jarrett L, Nandi P, Thompson AJ.
J Neurol Neurosurg Psychiatry 2002;73:705–709.

Intrathecal therapies, including baclofen and Phenol.
In: Stevenson VL, Jarrett L, editors. Spasticity management: a practical multidisciplinary guide.
London: Informa Healthcare; 2006. p.85-105.

Intrathecal Phenol: an old treatment revisited.
Pinder C, Bhakta B, Kodavali K.
Disabil Rehabil. 2008;30(5):381-6.

Spasticity in adults: management using botulinum toxin. National guidelines.
London: RCP. March 2018.

Management of spasticity with intrathecal Phenol injections: the past and the present
Anwar F, Antiga S, Mee H, Al Khayer A.
J Int Soc Phys Rehabil Med 2019;2(2):94-99.