



CLINICAL GUIDELINE

Aqueous Phenol (use of 6%) in unlicensed indications in pathological muscle hypertonia

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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Does this version include changes to clinical advice:	No
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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.

	<p align="center">NHS Greater Glasgow and Clyde Regional Services - NRU</p> <p align="center">Protocol for use of 6% Aqueous Phenol in unlicensed indications in pathological muscle hypertonia</p>
Background:	<p>Pathological Muscle Hypertonia as part of disordered motor control, like Spasticity and Dystonia, is common in conditions affecting the brain and spinal cord such as cerebral palsy (CP), acquired brain injury (ABI), stroke (CVA), multiple sclerosis (MS), hereditary spastic paraparesis (HSP), spinal cord injury (SCI) and others. Aqueous phenol is a recognised but unlicensed agent used in the focal treatment of spasticity and may be required to prevent loss of function, secondary complications, help manage pain or before rehabilitation goals can be met.</p>
Agent and route:	<p>6% Aqueous Phenol is used to complete upper or lower limb injections.</p>
License status:	<p>Aqueous phenol is classed as medium-risk unlicensed medicine.</p> <p>This protocol has been devised to cover use of Aqueous phenol in unlicensed indications in NRU. Approval for this protocol removes the requirement for individual ULM forms for each patient.</p> <p>A GGC ULM request is required for patients treated out with this policy.</p>
Indications for use:	<p>Where treatments such as oral medication, other focal injection therapy, therapy including splinting and stretching have been considered but not found to be best therapeutic choice in reducing focal/segmental spasticity.</p> <p>Aqueous phenol is indicated for use when :-</p> <ul style="list-style-type: none"> • A longer duration of effect is sought • Sensitivity or previous adverse reaction to Botulinum toxin A injections • Unsuccessful treatment using Botulinum toxin A • When the total dose of Botulinum toxin A would be excessive • Cost reduction
Treatment goals:	<p>Common treatment goals for intervention include:</p> <ul style="list-style-type: none"> • Reduction of pathological muscle hypertonia • Pain relief • Reduction of involuntary movements (e.g. associated reactions, spasms) • Prevention of contractures and deformity • Passive function (making it easier to care for the affected limb) • Active function (using the affected limb) • Mobility. <p>Patients will have a thorough and detailed assessment documented prior to receiving treatment.</p> <p>Outcome measure and SMART goals are recorded and reviewed within a month of treatment.</p> <p>Future treatment will be planned in accordance to goals.</p> <p>Treatment will be discontinued if goals are not achieved or if no response (as below).</p>
Authorised and designated areas applicable to:	<p>Patients may be treated within inpatient or outpatient settings in NHS GGC under the umbrella of Regional Services Directorate.</p>
Dose, duration and administration:	<p>In adults a maximum dose of 1g/17ml of 6 % Aqueous Phenol should not be exceeded in a day.</p> <p>Electrical stimulation and/or ultrasound are used to guide injection procedures using Aqueous Phenol.</p>

	For ambulant patients or for patients with any concern regarding potential effects of the treatment, a successful trial injection with Local anaesthetic could be undertaken first.
Administration & duration of effect:	The beneficial effect of treatment are expected to last for several months or longer. These benefits may be prolonged when used in combination with stretching, splinting or therapy.
Potential side effects:	<p><u>Spread of agent</u> Motor and sensory disturbance Paraesthesia Dysesthesia Acute pain</p> <p><u>Vascular complications</u> Necrosis of small arterioles DVT</p> <p><u>Overdose of agent</u> CNS depression Seizures</p> <p><u>Procedure-related injury</u> Localised infection, inflammation, hypoesthesia, tenderness, swelling, erythema, and/or bleeding/bruising. Needle-related pain and/or anxiety may result in vasovagal responses, e.g. syncope, hypotension, etc.</p>
Contraindications for use:	<p>The presence of infection or inflammation at the proposed injection site.</p> <p>Under active treatment with antibiotics due to infection.</p> <p>Avoid use in patients with subclinical or clinical evidence of defective neuromuscular transmission e.g. myasthenia gravis or Lambert-Eaton Syndrome.</p>
Cautions for use:	<p><u>General</u> Should be used with caution:</p> <ul style="list-style-type: none"> • in pregnancy • if bleeding disorders of any type occur • in patients receiving anticoagulant therapy or taking other substances that could have an anticoagulant effect. <p>NB If the patient is taking warfarin then the INR should be taken prior to the treatment and be ≤ 2.5 on day of injection. If patients target INR needs to be higher than this then liaise with anticoagulation clinic/Haematology.</p> <p>If the patient is taking other anticoagulants (such as apixaban, edoxaban, rivaroxaban, dabigatran), they would continue to take their normal dose.</p> <p><u>Pre-existing neurological conditions</u> Should only be used with extreme caution and under close supervision in patients with subclinical or clinical evidence of defective neuromuscular transmission e.g. myasthenia gravis or Lambert-Eaton Syndrome in patients with neurological disorders with muscle weakness / neuromuscular disorders (e.g. amyotrophic lateral sclerosis or motor neuropathy).</p> <p>Patients with a history of dysphagia, aspiration or breathing difficulties should be treated with extreme caution.</p> <p>In these patients, treatment must be administered only if the benefit of treatment outweighs the risk.</p> <p>Elderly and debilitated patients should be treated with caution.</p>
Authorised users:	NRU clinicians, including physicians and physiotherapist non-medical prescribers, who are competent in delivering Motor point or Nerve blocks.

Authorised for preparation in clinical area:	Staff preparing and administering phenol should wear PPE including goggles.
Authorised for storage in clinical areas:	Aqueous phenol should be stored within the controlled drug cupboard in NRU.
References:	<p>ALTER, K., HALLETT, M., KARP, B. & LUNGU, C., 2013. <i>Ultrasound-Guided Chemodenervation procedures text and atlas</i>. New York, Demos Medical Publishing.</p> <p>GAID, M., 2012. Phenol Nerve Block for the Management of Lower Limb Spasticity. <i>ACNR</i>. 12(3), pp. 23-5.</p> <p>ROY, C. 2012. Phenol Block for Upper Limb Spasticity. <i>ACNR</i> [online]. [viewed 19 February 2016]. Available from: http://www.acnr.co.uk/2012/12/phenol-block-for-upper-limb-spasticity/</p> <p>KEENAN, M., 1998. Management of the spastic upper extremity in the neurologically impaired adult. <i>Clinical Orthopaedics and Related Research</i>. 233, pp. 116-25.</p> <p>ELOVIC, E., ESQUENAZI, A., ALTER, K., LIN, J., ALFARO, A & KAE LIN, D., 2009. Chemodenervation and nerve blocks in the diagnosis and management of spasticity and muscle overactivity. <i>The American Academy of Physical Medicine and Rehabilitation</i>. 1, pp. 842-851.</p> <p>DEMIR, Y., SAN, AU., KESIKBURN, S., YASAR, E., & YILMAZ, B., 2018. The short-term effect of ultrasound and peripheral nerve stimulator-guided femoral nerve block with phenol on the outcomes of patients with traumatic spinal cord injury. <i>Spinal Cord</i>. 56(9): pp907-912.</p>
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Appendix 1;

Upper limb motor point blocks

Shoulder abduction/internal rotation

Subscapularis, pectoralis major, latissimus dorsi

Elbow flexion

Biceps, brachialis, brachioradialis

Wrist flexion

Flexor carpi radialis, flexor carpi ulnaris

Fingers flexion

flexor digitorum superficialis, flexor digitorum profundus

Thumb in palm

Flexor pollicis longus and brevis, adductor pollicis

1ml (60mg) injected at each identified motor point, with further small aliquots as needed, titrated to response.

It is rare for more than 2ml (120mg) to be needed at one motor point.

For motor points involving wrist and finger flexion total volume should not exceed 5ml (300mg).

UL nerve blocks

Elbow flexion (Biceps, brachioradialis muscles)

Musculocutaneous nerve: 2-3ml (120-180mg) injection, titrated to ablation of stimulation

Thumb in palm (Thenar eminence muscles)

Recurrent motor branch of the median nerve: 2-3ml (120-180mg) injection, titrated to ablation of stimulation

Lower limb motor point blocks

Knee Flexors

Hamstrings

Knee extensors

Quadriceps

Plantarflexor muscles

Gastrocnemius and soleus

1-3mls (60-180mgs) injected into each motor point, titrated to response and is also dependent on the size of the muscle

A maximum of 4-5 motor points should be injected again dependent on the response to stimulation

Lower limb nerve blocks

Hip adduction (Hip adductors)

Obturator nerve: 3.3-5ml (200 – 300mg) to each leg

Knee flexion (Hamstrings muscle)

Hamstring branches of sciatic nerve: 5-8.3ml (300-500mg) total, split between branches

Hip flexion/Knee extension (Quadriceps muscle)

Femoral nerve: 1.3-5ml (100-300mg) to each leg

Ankle equinovarus (Soleus, tibialis posterior, tibialis anterior muscles, toe muscles)

Tibial nerve or posterior tibial nerve: 1.3-3.3ml (100-200mg) to each leg

****MAXIMUM OF 17ML 6% AQUEOUS PHENOL IN ANY ONE DAY ****