Patient Group Direction

For the oral administration of iohexol (e.g., Omnipaque 240® and Omnipaque 300®) during video-fluoroscopy swallow studies

Reference: PGD 037

Written by: Rachael Shakespeare – Lead VSF Radiographer

Peer Reviewed by: Francesca Blakemore - Pharmacist

Approved: Feb 2024

Review Due: Feb 2029

Purpose

To provide guidance to the Speech and Language Therapy team on the administration of iohexol during video-fluoroscopy swallow studies.

Intended Audience

Speech and Language therapists, Radiographers, Radiology Aides & Radiologists working in the Radiology Department of Sheffield Childrens' NHS Foundation Trust

Table of Contents

1. Introduction

This patient group directive enables the administration of iohexol by authorized Speech and Language Therapists as part of videofluoroscopic studies.

2. Guideline Content

Referrals are made for children to undergo videofluoroscopic studies to assess the oropharyngeal phase of swallowing. All clinicians referring a child for VFS must have read this PGD and the Barium protocol to make sure patients are suitable for VFS before referral. Clinical details will be checked by the speech and language therapists, and if any further medical advice is needed or queries over suitability for the VSF arise the duty radiologist must be contacted. Where clinical indications are inappropriate then the referral will be declined.

Omnipaque 240/300 is the brand name and iohexol is the generic name of the active ingredient. Iohexol is a non-ionic, monomeric, triiodinated, water soluble x-ray contrast medium for diagnostic use only and should be used as an alternative to barium contrast for patients that are known to be at high risk of aspiration.

The Speech and Language therapist performing the examination will make all necessary identification and allergy checks with the patient or parent/carer.

Answers to identification and allergy checks must be recorded on the screening room checklist which will be scanned onto the Radiology Information System (RIS) to form part of the child's permanent medical record.

The Speech and Language Therapist must seek advice from a Consultant Radiologist if there is :-

1. A previous history of allergic reaction to non-ionic contrast
2. There is any uncertainty or ambiguity regarding the clinical details on the referral.

The Speech and Language Therapist should explain the risks and complications of the procedure: -

1. Aspiration of contrast
2. Allergic reaction to oral contrast (rare)

Patients thought to be at high risk of aspiration on IDDSI (International Dysphagia Diet Standardization Initiative) Level 0 - thin liquids - will be given non-ionic contrast iohexol for the first swallow. (As opposed to Barium under the protocol).

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction for the administration of Omnipaque 240® or Omnipaque 300® during video-fluoroscopy swallow studies by Speech and Language Therapists in Sheffield Children's NHS Foundation Trust

PGD development

Name	Job title and area of work within the trust		
Lead author	Rachael Shakespeare Radiographer		
Lead doctor (or dentist)	Iwan Roberts Radiologist		
Lead pharmacist	Francesca Blakemore		
Representative of other professional group using PGD	Nicky Sedgwick Speech and Language Therapist		
Other members of the PGD working group			

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior Doctor (or dentist)	Jeff Perring Medical Director		17/1/25
Senior pharmacist	Joanne Wragg Chief Pharmacist		18/1/25
Senior representative of professional group using the PGD	Jenny Longden Chief Nurse	Jenny Longden	17/01/25
Person signing on behalf of authorising body	Jeff Perring Medical Director		17/1/25

PGD revisions

If the PGD is revised:	Please list any changes from the previous PGD here
Changes in medical procedure	
Change in legislation	
Change in SPC of medicine	
other	Updated Template Updated clinical info Updated references

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Registration with RCSLT – Royal College of Speech and Language Therapists HCPC – Health and Care Professions Council
Initial training	To have completed RCSLT VFS competencies Understanding of this PGD
Competency assessment	Assessment by lead SLT
Ongoing training and competency	• Keep up to date with current best practice. Attend study days and conferences and adhere to any RCSLT guidance. • The SLT should be aware of any changes to the recommendations for Iohexol and current guidance from national authorities e.g the BNF-c and NICE. • It is the responsibility of the individual to keep up to date with CPD and to work within the limitations of their individual scope of practice.

Clinical Condition

Clinical condition or situation to which this PGD applies	The assessment of the oropharyngeal stage of swallowing via video-fluoroscopy
Inclusion criteria	Any child who is referred for a video-fluoroscopy study at Sheffield Children's NHS Foundation Trust and is at increased risk of aspiration.
Exclusion criteria	Hypersensitivity to iohexol or any other of the product excipients.
Cautions (including any relevant action to be taken)	• A history of allergy, asthma, or untoward reactions to iodinated contrast media. • Contrast induced nephropathy, impairment of renal function or acute renal failure. • Diabetic patients treated with metformin. • Disturbed thyroid function – due to the free iodine in iohexol • Patients with cardiac issues due to hemodynamic changes or arrhythmias. • Epilepsy – iohexol reduces seizure threshold. • Iohexol may aggravate symptoms of myasthenia gravis. • Patients with phaeochromocytoma may need alpha blockers to reduce the risk of a hypertensive crisis. If any if the above cautions apply advice from the duty radiologist should be sought.
Action to be taken if patient excluded	Contrast required for study, so if child unable to have contrast the study cannot be offered
Action to be taken if patient declines treatment	Contrast required for study, so if child unable to have contrast the study cannot be offered, and the child will be discharged from this pathway. Document in patient attendance record and inform clinical team responsible for patients care

Description of the Treatment

Name, form and strength of medicine	Omnipaque 240® Solution for injection 50mls Omnipaque 300® Solution for injection 50mls
Legal category	POM
Indicate any off-label use (if relevant)	Licensed medicine.

	Not a black triangle drug.
Route/method of administration	Oral Neat or mixed with squash to aid taste.
Dose and frequency	Given as IDDSI Level 0 thin liquid. Iohexol 240 • < 3 months: Up to 20ml Iohexol 240 or 300 • 3 months to 3 years: Up to 60ml • 4 to 10 years: Up to 80 ml • >10 years and Adolescents: Up to 100 ml. Iohexol 300 should be used if flavoring (squash) is added unless child is under 3 months.
Maximum or minimum treatment period	VFS study lasts 30minutes. Only one dose to be given as above.
Drug Interactions	• Interleukin-2 and interferons - increased risk of a delayed reaction if these drugs have been used within the last 2 weeks. (erythema, flu-like symptoms or skin reactions). • Antipsychotic drugs or tricyclic antidepressants – reduce the seizure threshold. • β-blockers – lower the threshold for hypersensitivity reactions as well as patient needing higher doses of B agonists when treating the reactions. • β-blockers along with angiotensin-converting enzyme inhibitors and angiotensin receptor antagonists reduce the efficacy of cardiovascular compensation mechanisms of blood pressure changes • All iodinated contrast media may interfere with tests on thyroid function; thus the iodine binding capacity of the thyroid may be reduced for up to several weeks. • High concentrations of contrast media in serum and urine can interfere with laboratory tests for bilirubin, proteins or inorganic

	substances (e.g. iron, copper, calcium and phosphate). These substances should therefore not be assayed on the day of examination. • Contrast induced nephropathy may be problematic in patients who take Metformin. NOTE: Contact Pharmacy for advice if needed on drug class or a potential drug interaction.
Adverse effects	Anaphylaxis, headache, metallic taste, syncope, bradycardia, hypertension, hypotension, nausea, salivary gland enlargement, feeling hot or cold, sweating, pyrexia, shivering, vasovagal reactions including pale skin, light-headedness, tunnel vision, blurred vision, diarrhoea, vomiting, pain around stomach area. Transient hypothyroidism has been reported in premature infants, neonates, and other children. Symptoms usually occur within minutes to hours after administration of iohexol, and generally resolve within days.
Storage	Room temperature protected from light in a locked medicine cupboard.
Records to be kept	The screening room checklist will be scanned onto the RIS and will include details of contrast including name, strength and volume used (with sticker from the bottle)

Patient information

Written information to be given to patient or carer	None
Follow-up advice to be given to patient or carer	Maintain adequate hydration. If parent/child are worried about any side effects that persist, contact GP or the child's specialist team in the usual way.

Audit arrangements	As per current Trust PGD Policy
References	GE Healthcare Limited, Omnipaque Injection 240mg I/ml solution for injection. Date of revision of the text 05/11/2023. Available at Omnipaque Injection 240mg I/ml solution for injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) GE Healthcare Limited, Omnipaque Injection 300mg I/ml solution for injection. Date of revision of the text 05/11/2023. Available at Omnipaque Injection 300mg I/ml solution for injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Lexicomp Iohexol. Paediatric and Neonatal Lexi-Drugs. Wolters Kluwer Health, Inc, Riverwoods, IL. Available at Iohexol (Pediatric and Neonatal Lexi-Drugs) - Lexicomp. Accessed 13/02/2024

Staff authorised to work under this PGD	
Ward / Department	Identify which area of the Trust the PGD is to be used
Professionals to whom this Patient Group Direction applies	Identify the staff group working under the PGD

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:

Name (Capitals)	Sign	Job Title	Authorising Manager	Date

When the review date is exceeded, this PGD ceases to be an approved Trust document