University Hospitals of Derby and Burton NHS Foundation Trust

PROTOCOL

For Physiologist Led Left Ventricular Opacification Contrast Echocardiography By Advanced Cardiac Physiologists in the Clinical Measurements Department at Royal Derby Hospital.

Documentation details

Reference no:	UHDB204
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Change history

Version number	Change details	Date
3	In-patient Physiology led LVO service added. Change to Consultant Cardiologist	15/06/2022

Glossary

Abbreviation	Definition
LVO	Left Ventricular opacification
BSE	British Society of Echocardiography
TTE	Transthoracic Echocardiogram

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
Dr Nauman Ahmed	Consultant Cardiologist
Dr Surojit Bose	Consultant Cardiologist
Claire Nieuwoudt	Advanced Cardiac Physiologist
James Kerr	Divisional Lead Pharmacist

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
Advanced Cardiac Physiologist in Echocardiography – Physiology led LVO service
Limitations to authorisation
This protocol can only be followed once a patient specific direction has been issued from a prescriber relating to this procedure. This organisation does not authorise the use of this Protocol by any Physiologist that is not a band 7 or above and who has not completed the relevant training.
Agreed rationale for protocol use in place of a PGD (Patient Group Direction)
Physiologists are not legally permitted to operate under PGDs. This protocol provides a framework to assess patient for administration after a patient specific direction (from a prescriber) has been received to authorise use of this prescription medicine for this procedure. The Trust Medicines Policy (2022) includes formal exemption to allow appropriately trained physiologists to prepare and administer intravenous medicine for this procedure.

Organisational Authorisation			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer	James Hooley	Signed copy held by Pharmacy	17/10/2022

Additional signatories			
Role	**Name**	**Sign**	**Date**
Divisional Lead Pharmacist	James Kerr	Signed copy held by Pharmacy	**20/09/2022**
Lead Consultant Cardiologist	Dr Surojit Bose	Signed copy held by Pharmacy	**06/10/2022**
Lead Advanced Cardiac Physiologist	Claire Nieuwoudt	Signed copy held by Pharmacy	**29/09/2022**

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	Cardiac Physiologists who are members of the Registration Council of Clinical Physiologists (RCCP) and /or hold the adult transthoracic British Society of Echocardiography (BSE) Accreditation for > 2 years.
Initial training	• Individual has read and understood full content of this Protocol and signed authorisation (section 7). • Completion of Trust Cannulation course. • ILS up to date including clinical signs and treatment of anaphylaxis (or alternative resus training which incorporates BLS + AED + anaphylaxis). • Attended the Trust IV therapy course including specific training for the administration of sonovue. • Completing all scope documentation required. • Up-to-date trust ANTT and hand hygiene.
Competency assessment	The Physiologist will be 100% supervised by either a Lead Advanced Physiologist (> 6months experience) or Cardiac Imaging Consultant until they have completed all courses, scope documents, produced a log book of 20 patients and deemed competent. All patients will be included on the audit sheet to be able to audit complication rates. 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	Once signed off as being competent the first 25 patients performed will be audited by the Lead Physiologist. 10% will be audited thereafter. Practitioner should be aware of any change to the recommendations for Sonovue. It is the responsibility of the individual to keep up-to-date with their CPD, actively taking part and annual individual performance reviews. Continued BSE training via attending courses and long distance learning modules in order to maintain Full BSE Accreditation. Reaccredit with the BSE every 5 years. Yearly resus training (as above), ANTT and hand hygiene. Maintain Cannulation competencies
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	Administration of Sonovue for enhanced opacification of the Left Ventricle for accurate assessment of LV ejection fraction and visualisation of LV thrombus when 2D transthoracic Echocardiography images are suboptimal
Criteria for inclusion	This medicinal product is for diagnostic use only and this is inclusive of left ventricle opacification echocardiography studies. SonoVue is for use with ultrasound imaging to enhance the echogenicity of the blood, which results in an improved signal to noise ratio. SonoVue should only be used in patients where study without contrast enhancement is inconclusive. **Echocardiography:** SonoVue is a transpulmonary echocardiographic contrast agent for use in patients with suspected or established cardiovascular disease to provide opacification of cardiac chambers and enhance left ventricular endocardial border delineation
Criteria for exclusion	• Hypersensitivity to the active substance(s) or to any of the excipients contained within the preparation. *SonoVue is contraindicated in patients known to have* • right-to-left shunts • severe pulmonary hypertension (pulmonary artery pressure > 90 mmHg) • uncontrolled systemic hypertension • patients with adult respiratory distress syndrome. • Sonovue should not be used in combination with dobutamine in patients with conditions suggesting cardiovascular instability where dobutamine is contraindicated. • The safety and efficacy of SonoVue have not been established in pregnant and lactating women therefore, SonoVue should not be administered during pregnancy and lactation. *Sonvue is recommended to be administered with extreme caution in the following patients (and is therefore outside of scope for clinical physiologists to perform autonomously[2]):* • recent acute coronary syndrome or clinically unstable ischaemic . • cardiac disease, including: evolving or ongoing myocardial infarction, typical angina at rest within last 7 days, significant worsening of cardiac symptoms within last 7 days, recent coronary artery intervention or other factors suggesting clinical instability (for example, recent deterioration of ECG, laboratory or clinical findings) • acute cardiac failure • Class III/IV cardiac failure • severe rhythm disorders because in these patients allergy-like and/or vasodilatory reactions may lead to life threatening conditions. SonoVue should only be administered to such patients after careful risk/benefit assessment **by a prescriber** and requires close monitoring of vital signs to be performed during and after any administration.

Cautions including any relevant action to be taken	3 lead ECG monitor for all patients throughout test All resuscitation equipment readily available outside the room including oxygen, suction, defibrillator, resuscitation trolley and anaphylaxis grab box. Cardiac arrest team available. Caution is advisable when administering the product to patients with: • acute endocarditis • prosthetic valves • acute systemic inflammation and/or sepsis • hyperactive coagulation states and/or recent thromboembolism • end-stage renal or hepatic disease As the numbers of patients with those conditions who were exposed to SonoVue in the clinical trials were limited. ***Pregnancy:*** No clinical data on exposed pregnancies are available. Animal studies do not indicate harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. As a precautionary measure, it is preferable to avoid the use of SonoVue during pregnancy. ***Breastfeeding:*** It is not known if sulphur hexafluoride is excreted in human milk. However, based on its rapid elimination from the body via the expired air, it is considered that the breastfeeding can be resumed two to three hours after administration of SonoVue.
Action to be taken if the patient is excluded	Refer back to referring consultant and document reasons on cardiobase
Action to be taken if the patient or carer declines treatment	Refer back to referring consultant and document reasons on cardiobase
Arrangements for referral for medical advice	Seek medical advice if any concern with patients condition

5. Description of treatment

Name, strength & formulation of drug	Sulphur hexafluoride 8 microlitres/ml Powder and solvent for dispersion for injection 1 vial 25mg lyophilised powder 1 pre-filled syringe 5ml sodium chloride
Legal category	POM
Route / method of administration	The microbubble dispersion is prepared before use by injecting through the septum 5 ml of sodium chloride 0.9% solution for injection to the contents of the vial. The vial is then shaken vigorously for a few seconds until the lyophilisate is completely dissolved. The desired volume of the dispersion can be drawn into a

	syringe any time up to six hours after reconstitution. Just before drawing into the syringe, the vial should be agitated to re-suspend the microbubbles. SonoVue should be administered immediately after drawing into the syringe by injection into a peripheral vein. Every injection should be followed by a flush with 5 ml of sodium chloride 0.9% solution for injection.
Indicate any unlicensed or off-label use (if relevant)	*Maximal dosing in this protocol is above licensed dosing. It is supported in the scope package developed with the medical team[2].*
Dose and frequency of administration	Inject 0.5 to 1ml bolus Follow by 2 to 5mls of sodium chloride 0.9% until contrast is seen in the right heart. Inject additional top up doses as needed in increments of 0.5ml Max 5ml of SonoVue
Duration of treatment	The intensity of the reflected signal is dependent on concentration of the micro bubbles and frequency of the ultrasound beam. At the proposed does SonoVue provides a marked increase in signal intensity for 2 minutes for B - mode imaging in echocardiography. Additional doses up to maximum of 5mls can be administered to ensure adequate images of LV walls are obtained.
Quantity to be supplied (leave blank if protocol is administration ONLY)	
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: The medicinal product does not require any special storage conditions.www.medicines.org.uk
Drug interactions	**Drug Interactions/Severity:** No interaction studies have been performed. There was no apparent relationship with respect to occurrence of adverse events in the clinical studies for patients receiving various categories of the most common concomitant medications. **Precautions:** Caution is advised when Sonovue is administered to patients with clinically significant pulmonary disease, including severe chronic obstructive pulmonary disease**.**
Identification & management of adverse reactions	**Adverse Effects** following SonoVue administration are rare and uncommon, however, can include: • Headache • Paraesthesia • Dizziness • Dysgeusia • Flushing • Pharyngitis • Nausea • Pruritis • Rash • back pain • chest pain • chest discomfort

	• Pain • Fatigue • injection site reaction • feeling hot Other rare adverse drug reactions reported include: • insomnia, • blurred vision • hypotension • abdominal pain. Anaphylaxis is rare but full resuscitation equipment and trust resuscitation team to be called with any suspicion of anaphylaxic response. Anaphylaxic drug box immediately available.
Management of and reporting procedure for adverse reactions	• 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. • Adverse reaction to SonoVue is most likely to be within the first few minutes of administration. Anaphylaxis is rare but full resuscitation equipment and trust resuscitation team to be called with any suspicion of anaphylaxic response. Anaphylaxic drug box immediately available. • Discuss with on – call cardiology registrar regarding medical issues on day
Written information to be given to patient or carer	Patient information sheet available to patient prior to test. With full explanation of test and why they have been referred on the day.
Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management, and if an in-patient, inform named nurse or doctor of the risks associated with Sonovue with emphasis on the risk of anaphylaxis. Verbal consent with clarification of risk prior to commencing test. The individual/carer should be advised to seek medical advice in the event of an adverse reaction. An adverse reaction to Sonovue is most likely to be within the first few minutes of administration, however all out-patients are to sit within the waiting area for 30 minutes after the study with their cannular still in-situ, the cannular is only removed after 30 minutes and the patient has shown no side effects. If they are In-patients they will be asked to stay on their beds for 30 mins, with their nurse call buttons next to them, their named nurse or doctor on the ward will be informed that Contrast has been given and the delay risk of an allergic reaction
Records	Either the system holding the record, or the healthcare practitioner working under the Protocol, must capture/document all of the following:

	• name of the health professional providing treatment • patient identifiers (name of individual, address, date of birth and GP with whom the individual is registered (if relevant)) • name of the medicine supplied/administered • date the medicine is supplied/administered • dose, form and route of supply/administration • batch number and expiry date • patient consent or refusal • patient inclusion or exclusion from PROTOCOL • information/advice given to the patient • details of any adverse drug reactions including action taken • state any other agreed records to be kept for audit purposes Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. For EPMA: Document the utilisation of the medicine under PROTOCOL by ordering the appropriate drug order item against the correct patient record in iCM/Lorenzo. Complete all mandated fields on the prescription form, identified by a blue star. Document the administration of the medicine in the worklist manager. 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	1. https://www.medicines.org.uk/emc/product/1539 2. *UHDB. Left Ventricle Opacification Contrast Echocardiography Studies (LVOCE) - Scope of Practice Package.*

7. Registered health professional authorisation sheet

Protocol [version]: Clinical Measurements Department – Physiologist Led Left Ventricular Opacification Contrast [v3]
Protocol ref: UHDB204

Valid from: 17/10/2022 Expiry date: 16/10/2025

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 protocol 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.