RHiNO Trial

Cardiff & Vale University Health Board
University Hospital of Wales
Heath Park
Cardiff, CF14 4XW

Patient Group Direction (PGD) for the Administration of Inhaled Salbutamol for Reversibility Testing in Children Participating in Home Screening for the RHiNO Trial

PGD comes into effect	22nd August 2016
Review date	22nd August 2018
Expiry date	22nd August 2018
Name of Medicine	Salbutamol
Professionals to which PGD applies	Registered nurses employed within Cardiff & Vale University Health Board working as part of the RHiNO (Respiratory Health outcomes in Neonates) trial team who have received appropriate training and demonstrated competency
Clinical Director for Women and Child Heath	
On behalf of Cardiff & Vale University Health Board Service Director for Pharmacy and Medicines Management	
Medical Director	
Nurse Director	

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Clinical Condition	This PGD applies to well children who are undertaking reversibility testing as part of the Medical Research Council (MRC) funded RHiNO trial.
Criteria for Inclusion	Children who have met the inclusion criteria for the RHiNO trial for whom informed parental consent and child assent has been gained as per Good Clinical Practice (GCP) guidance.
Criteria for exclusion	All children who are not participating in the RHiNO trial, or have been excluded as per research protocol. Children with a known hypersensitivity to a beta 2 adrenoceptor stimulant drug. All adults.
Seek further advice	Further advice must be sought from the medical staff within the research team if there are concerns about prior cardiac disease – in particular arrhythmias, diabetes or hyperthyroidism. Advice must be sought for patients taking any of the following medications; Digoxin, aminophylline, corticosteroids, diuretics, and theophylline.

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Description of treatment	The RHiNO study, funded by the MRC after robust peer review, is designed to evaluate the lung function of children aged between 7 and 12 years old who were born prematurely (<= 34 weeks gestation). 1,000 Children born prematurely will be recruited following completion of a survey during which they will agree to participate in further testing. A small number of term-born children will also be recruited to act as controls. As part of this study, these well children will be subject to a series of tests during a one-off home visit. This home visit will be undertaken by a member of the RHiNO trial team (primarily dedicated research nurses). A key component of this visit will be lung function testing. This will include reversibility testing as outlined by the British Thoracic Society (BTS), during which inhaled Salbutamol via a paediatric spacer device will be administered. The team member undertaking this test will undertake an initial assessment alongside a short medical history prior to testing. Following testing a further assessment will be undertaken to ensure the child remains well.
Name of medicine	Salbutamol
Class of medicinal product	Selective beta-2 agonist
Legal status of Medicine	Prescription Only Medicine
Form	Metered dose inhalation via paediatric spacer device

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Strength	100 micrograms per actuation
Dosage	4 actuations – Total dose 400 micrograms
Total daily dose	Dose only given once during reversibility testing
Route of administration	Inhalation via paediatric spacer device
Frequency of administration	Dose only given once during reversibility testing
Duration of treatment	Dose only given once during reversibility testing
Total treatment quantity	Total Dose of 400micrograms given on one occasion during reversibility testing as part of lung function testing as per BTS guidance. Four metered doses of 100 micrograms will be given via paediatric spacer and appropriate mouthpiece, with the child being instructed to take 10 normal breaths through the device for each actuation.

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Adverse reactions	♦ Common (>= 1/100 to < 1/10) ♦ Tremor, headache, tachycardia, ♦ Uncommon (>=1/1000 to <1/100) ♦ Palpitations, mouth and throat irritation, muscle cramps ♦ Rare (>=1/10,000 to <1/1000) ♦ Peripheral vasodilation, hypokalaemia, ♦ Very Rare (<1/10,000) ♦ Hyperactivity, paradoxical bronchospasm, cardiac Arrhythmias, hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse There is some evidence of rare occurrence of myocardial ischaemia associated with Salbutamol. The incidence is unknown.
Written & verbal advice for patient/carer	♦ Patient Information Leaflet (PIL) given to all participants ♦ Reassurance for more common side effects such as fine tremor, headache, tachycardia/palpitation
Follow up	Nurse to remain with participant until testing completed. Vital signs and general heath check prior to completion of

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	visit/testing.
Arrangements for referral for medical advice	In unlikely event of sudden collapse emergency help will be summoned (i.e. ambulance). All nurses will have completed a paediatric immediate life support course and be trained in recognising and treating anaphylaxis. They will carry and administer emergency adrenaline (EpiPen) in line with the Human Medicines Act to enable early treatment until ambulance arrives. Any adverse event will be documented on the Case Report Form (CRF) and online via the UHB Trust Datex system. Reporting will also be undertaken to the Committee on the Safety of Medicines using the Yellow card system. The child's GP will be informed of any significant adverse event.
Records of administration for audit	The following information will be documented in the individual participant research notes: ♦ Date of administration ♦ Dose given ♦ Route and method of administration ♦ Batch number and expiry date ♦ Signature of nurse administering ♦ Outcome – including observations post testing and general health check

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Staff

Professional qualifications	Registered Children's Nurse
Training	All staff to have undertaken training in the use of PGD's for the purpose of reversibility testing. All staff will have completed the Resuscitation Council Paediatric Immediate Life Support (PILS) or Advanced Paediatric Life Support Courses All staff to have undertaken training in the recognition of and treatment for anaphylaxis and the use of emergency adrenaline. All staff to have undertaken training in spirometry testing. All staff to have undertaken GCP in research training.
Continuing education	All staff must be aware of any changes related to the recommendations for use of Salbutamol in reversibility testing. All staff must ensure that they are conversant with ongoing notifications related to the safety of using Salbutamol in this patient group and any new recommendations that affects the administration of this medication. They must also ensure that they are aware of and changes within the research protocol that may impact upon the use of this PGD. It is the responsibility of staff to ensure that they ensure they take responsibility for continued professional development.

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Signature of individual accepting responsibility and accountability to perform this PGD	