Trust Protocol for the Administration of Intravenous Methylprednisolone for Thyroid Eye Disease

A Protocol

For Use in:	The Clinical Investigation Unit (CIU)
By:	Named Endocrine Specialist Nurses
For:	Endocrine patients with thyroid eye disease
Division responsible for document:	Medical Division (Including Emergency)
Key words:	Intravenous methylprednisolone, Thyroid eye disease
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Assessed and approved by the:	Clinical Guidelines Assessment Panel (CGAP) If approved by committee or Governance Lead Chair's Action; tick here ☑
Date of approval:	05/02/2019
Ratified by or reported as approved to (if applicable)**:**	Clinical Standards Group and Effectiveness Sub-Board
To be reviewed before: This document remains current after this date but will be under review	05/02/2022
To be reviewed by:	Katherine Powell
Reference and / or Trust Docs ID No:	CIU5 – id 8979
Version No:	4
Description of changes:	Information on milk proteins added
Compliance links: *(is there any NICE related to guidance)*	None
If Yes - does the strategy/policy deviate from the recommendations of NICE? If so why?	No

This guideline has been approved by the Trust's Clinical Guidelines Assessment Panel as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes.

The Trust's guidelines are made publicly available as part of the collective endeavour to continuously improve the quality of healthcare through sharing medical experience and knowledge. The Trust accepts no responsibility for any misunderstanding or misapplication of this document.

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Objective

To enable patients to have an intravenous infusion of methylprednisolone for the treatment of thyroid orbitopathy safely and efficiently by appropriately trained nurses on the Clinical Investigation Unit.

Rationale

Methylprednisolone may be given for conditions in which a rapid, intense glucocorticoid effect is required for the treatment and management of either severe acute or chronic inflammatory thyroid eye disease.

Broad recommendations

- The infusion of high dose methylprednisolone will only be administered on patients referred by a Consultant Ophthalmologist or Specialist Registrar in Ophthalmology. **Other referrals will not be accepted.**
- The infusion should not be given if patients have received prednisolone >50mg orally within the preceding week.
- Patients with diabetes will require individualised advice on blood glucose monitoring after this infusion.

It is the responsibility of the referring Doctor to:

a) Clearly indicate the dose of methylprednisolone to be administered on each occasion.

b) Ensure there are no clinical contraindications, including abnormal liver function tests, and urea and electrolytes.

If in doubt about the safety of performing this infusion on a patient the Endocrine Specialist Nurse should discuss concerns with the referring Doctor or the Specialist Registrar.

It is the responsibility of the Endocrine Specialist Nurse to:

a) Ensure that the dose of methylprednisolone has been prescribed. Ensure that liver function tests and urea and electrolytes are ALL normal or have been reviewed by referring clinician or specialist registrar and there is documentation in the notes that it is safe to proceed.

Administration

1. Prior to administration of intravenous methylprednisolone, baseline observations including pulse, blood pressure, respiratory rate, oxygen

saturations and finger prick blood glucose readings should be recorded. If any of these readings are not within normal parameters seek medical advice.

2. Check results of liver function test and urea and electrolytes from previous week (after week 1). If ALL results are normal proceed with infusion. If ANY results are abnormal there must be documented evidence that the referring doctor or specialist registrar has reviewed them and is happy for the infusion to proceed.
3. Insert a cannula according to Trust Policy for Peripheral Intravenous Cannulation and Cannula care in Adults.
4. Take blood sample for Liver Function Test and urea and electrolytes to be checked prior to next infusion.
5. Reconstitute methylprednisolone using diluent provided.
6. Add reconstituted methylprednisolone to 100ml of 0.9% Normal Saline using an aseptic technique.
7. Methylprednisolone in doses ≥ 250mg should be infused, using an infusion pump, slowly over at least 30 minutes to avoid the possibility of cardiovascular toxicity.
8. On completion of infusion, flush cannula and remove.
9. Repeat observations.
10. For patients with known diabetes give advice on blood glucose monitoring and fluid intake as below:

Caution

Arrhythmia, cardiac arrest and circulatory collapse may be associated with rapid infusion.

Methylprednisolone injectable medicine containing lactose (Solu-Medrone 40mg may contain trace amounts of milk proteins. Do NOT use in patients with a known or suspected allergy to cow's milk.

Glycaemic control is likely to deteriorate temporarily following high dose methylprednisolone.

There may also be a rise in blood pressure and if the nurse has any concerns she should discuss this with one of the Specialist Registrars.

Patients may also experience weight gain.

Patients with known diabetes

- Patients with known diabetes referred for methylprednisolone should have been warned by the referring consultant that their blood glucose control may decline rapidly, and that insulin therapy may occasionally be needed in the short term.
- Patients with known diabetes on insulin should be discussed with a Diabetes Specialist Registrar or their usual Diabetes Specialist Nurse for advice before

the methylprednisolone is administered wherever possible. Patients should be warned that their insulin doses may need to change rapidly and substantially on a temporary basis after the treatment. They should also be advised to check their blood glucose at least twice daily, and urine ketones once daily for 7 days after the treatment, and should contact their diabetes specialist nurse or practice nurse if glycaemic control declines, symptoms of hyperglycaemia develop or if they develop ketonuria.

Patients with Type 2 diabetes on diet or tablets alone should be shown how to monitor blood glucose twice daily, i.e. before breakfast and before evening meal for 7 days after each dose of pulsed methylprednisolone. They should then be advised to contact their usual diabetes team (usually a GP or practice nurse) if they develop symptoms of hyperglycaemia or if their blood glucose is >12mmol/l for >24hrs.

Staff selection and training

- Nursing staff working to this protocol in the Clinical Investigation Unit will be a qualified registered nurse, band 5 or above.
- They must have completed their preceptorship.
- They must have completed the IV therapy and cannulation study days and been assessed as competent to administer IV therapy and to cannulate.
- All designated nurses will be assessed as competent to independently perform these infusions by the Endocrine Specialist Nurse through supervised infusions. They will be able to demonstrate verbally to the Endocrine Specialist Nurse, knowledge underpinning the reason why the infusion is being performed, and be able to discuss any potential complications and how each patient is monitored.

Register of staff

The details of each member of staff working to this protocol must be retained on a 'live' departmental register (Appendix 1) held within the Clinical Investigation Unit. It is the department's responsibility to keep the register up to date.

Clinical Audit Standards

To ensure that this policy is compliant with the above standards, the following monitoring processes will be undertaken:

- Weekly meetings are held between the Endocrine Specialist Nurses and the Endocrine Clinicians where it is possible to discuss any actual or potential problems with any activity undertaken in the Clinical Investigation Unit.
- In the event of an adverse incident, an incident form is completed online and logged if necessary at Clinical Governance. It will also be discussed at the monthly Endocrine Meeting.
- A record will be kept of the number of infusions performed, together with any complications, for audit purposes.

The audit results will be sent to the Lead Consultant, Endocrinologist who will ensure that these are discussed at relevant governance meetings to review the results and make recommendations for further action.

Distribution list/ dissemination method

Clinical Investigation Unit
Practice Development and Education Department.
Individual Practitioners
Trust Intranet via 'Trust Docs'

Source Documents

Consensus Statement of the European Group on Graves' Orbitopathy (EUGOGO) on Management of Graves' Orbitopathy (2008).

MHRA Drug Safety Update October 2017

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Appendix 1

Departmental Record of Signatories

This is the departmental list of all those who have read and agreed to act within the parameters of this protocol. Each individual has kept a signed copy of the protocol for his / herself.

Print Name	Sign	Date *dd/mm/yyyy*