Clinical Procedure for the Administration of Intravenous Methylprednisolone for Thyroid Eye Disease

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Version	Date	Author	Reason/Change
V1.0	02/2013	Endocrine Specialist Nurse	To originate document
V2.0	05/2015	Endocrine Specialist Nurse	superseded
V3.0	02/2016	Endocrine Specialist Nurse	superseded
V4.0	02/2019	Endocrine Specialist Nurse	Superseded -Information on milk proteins added
V5.0	07/2023	Senior Endocrine Specialist Nurse	Addition to section 1.3.1 and author name updated. Document transferred to new Trust procedural document template.

Previous Titles for this Document:

Previous Title/Amalgamated Titles	Date Revised
None	Not applicable

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:

- Consultant Ophthalmologist
- Endocrine Specialist Nurse
- Clinical Governance Meeting of the Directorate of Endocrinology
- Consultant Endocrinologists

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a clinical guideline applicable to Norfolk and Norwich University Hospitals NHS Foundation Trust; please refer to local Trust's procedural documents for further guidance.

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1. Introduction

1.1. 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.

1.2. 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.

1.3. Scope

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.

1.3.1. 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.

c) Check HbA1c prior and on completion of the course of treatment.

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.

1.4. Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
CIU	Clinical Investigations Unit
HbA1c	Diabetes test
GP	General Practitioner
IV	Intravenous

2. Responsibilities

a) Consultant Ophthalmologist

b) Senior Endocrine Specialist nurse – author of document and distribution once fully approved.

c) Lead Consultant for Endocrinology – Support in producing the document and lead for the Endocrine business meeting.

d) Lead for Clinical Governance in Endocrine & Diabetes – For approval at speciality level.

e) Clinical Director for Endocrine & Diabetes – for overall approval

3. Processes to be followed

3.1. 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:

3.1.1. 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.

3.2. 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.

4. Training & Competencies

- 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.

4.1. 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.

5. References

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

MHRA Drug Safety Update October 2017

6. Monitoring Compliance

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Meetings between Endocrine Specialist Nurses and Endocrine Clinicians to discuss any actual or potential problems with any activity undertaken in the CIU	Weekly meetings	Endocrine Specialist Nurses and Endocrine Clinicians	Endocrinology	Weekly
Adverse Incident Recording	Incident Forms completed online	Endocrine Meetings	Clinical Governance	Monthly
Records of the number of infusions performed and any complications	Records / Log	Nurses	Governance Meetings	Monthly

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

7. Distribution list/ dissemination method

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

8. Appendices

8.1. 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 themselves.

Print Name	Sign	Date dd/mm/yyyy

9. Equality Impact Assessment (EIA)

Type of function or policy	Existing		
Division	Medical	**Department**	Endocrinology
Name of person completing form	Neetha Joseph	**Date**	

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	No	No	None	No
Pregnancy & Maternity	Yes, many hormone levels change during pregnancy it is the referring clinician's responsibility to only refer patients for tests where pregnancy will not affect the results	No	All pregnant women	No
Disability	No	No	None	No
Religion and beliefs	No	No	None	No
Sex	No	No	None	No
Gender reassignment	No	No	None	No
Sexual Orientation	No	No	None	No
Age	This document is for adults (over 16) only	No	None	No
Marriage & Civil Partnership	No	No	None	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?				

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.