Norfolk and Norwich University Hospitals NHS Foundation Trust

James Paget University Hospitals NHS Foundation Trust

Joint Trust Guideline for the Management of Methylprednisolone Sodium Succinate Infusion for Child or Young Person

A Clinical Guideline

For use in:	Children's Department
By:	Registered Paediatric Nurses and Medical Staff
For:	Children with active inflammatory bowel disease, allergic bronchopulmonary aspergillosis (ABPA), childhood interstitial lung disease (CHILD), active rheumatological conditions, or other conditions requiring rapid immunosuppression.
Division responsible for document:	Paediatrics
Key words:	Methylprednisolone Sodium Succinate Infusion, inflammatory bowel disease, juvenile idiopathic arthritis, ulcerative colitis, Crohns disease, allergic bronchopulmonary aspergillosis, interstitial lung disease
Name and job title of document author's:	Catherine Tranter, Lead Paediatric Rheumatology Specialist Nurse, Catharine Searle, Children's Gastroenterology Specialist Nurse, Dr Peter Bale, Consultant Paediatrician
Name and job title of document author's Line Manager:	Dr Aravind Shastri, Consultant Paediatrician (Cardiology/Rheumatology), Service Director for Paediatrics
Supported by:	Dr Kate Armon, Consultant Paediatric Rheumatologist Dr Stephen Nirmal, Paediatric Consultant (JPUH) Dr Anjay Pillai, Consultant in Paediatric Respiratory Medicine
Assessed and approved by the:	Medicines Management Clinical Guidelines and Assessment Panel (CGAP) If approved by committee or Governance Lead Chair's Action; tick here ☑
Date of approval:	11/02/2022
Ratified by or reported as approved to (if applicable)**:**	Clinical Safety and Effectiveness Sub-Board
To be reviewed before:	1/02/2025
To be reviewed by:	Dr Peter Bale/Dr A Shastri
Reference and / or Trust Docs ID No:	JCG0049 ID: 1269
Version No:	2.6
Compliance links:	None
If Yes – does the strategy/policy deviate from the recommendations of NICE? If so why?	N/A

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.

Version and Document Control:

Version Number	Date of Update	Change Description	Authors
2.4	24/12/2020	No clinical changes at this time, but a one year review date given, as awaiting regional guidance.	Dr Kate Armon. Catherine Tranter, Catharine Searle, Dr Peter Bale
2.5	29/04/2021	JPUH lead amended	Catherine Tranter,
2.6	July 2021	Respiratory indications and doses added. Gastroenterology and rheumatology made some minor changes	Dr Anjay Pillai Dr Kate Armon Dr M. A Morris
2.6	Jan 2022	Normal saline amended to sodium chloride 0.9% and other minor amendments	Dr A Shastri Catherine Tranter,

This is a Controlled Document

Printed copies of this document may not be up to date. Please check the hospital intranet for the latest version and destroy all previous versions.

Objectives of Guideline

To ensure the safe administration and monitoring of methylprednisolone sodium succinate by qualified nursing staff.

Rationale for the recommendations

Safe administration of methylprednisolone in children and young people.

Broad recommendations

- Decision to start methylprednisolone will be taken by the responsible consultant after counselling of patient and parents.
- Patients requiring Methylprednisolone will usually have 3 doses, by once daily infusion. An overnight stay for observation on the first occasion the patient receives this treatment is standard practice, but the treating consultant will decide on an individual patient basis.
- Patient to be clerked prior to each infusion. Methylprednisolone must not be given if any signs of acute infection are present, or the patient has an active peptic ulcer.
- Methylprednisolone should only be used during pregnancy after discussion with the relevant consultant.
- Individual doses may be prescribed by a paediatric doctor in accordance with these guidelines.
- Clinical response should be assessed after the 3rd dose by the responsible team, and a plan made before change to regular oral prednisolone where applicable.

- Administration of methylprednisolone is appropriate as a day case on Children's Day Ward (CDW)/Buxton ward/Children's Assessment Unit (CAU).
- Only qualified nurses who are intravenously trained should administer treatment.
- The date for any blood monitoring and follow up appointment should be arranged before the patient is discharged home.

Dosage and administration

Dose varies depending on the indication

Rheumatology indications

Methylprednisolone sodium succinate 10-30 mg/kg/day (maximum 1000mg) once a day for three days (dose will be determined by the responsible consultant and clearly documented).

10-19mg/kg: Dilute in 100mL sodium chloride 0.9% and give intravenously over 30 minutes.

20-30mg/kg: For those getting higher doses especially 30 mg/kg/day, this is preferably given over at least 2 hours. Confirm the dose from the notes / responsible consultant's team, as it may vary dependent on the indication and clinical status of the child / young person.

For the first infusion only, should run slowly over 4 hours (under 35kg) and over 2 hours (for weight >35kg).

Respiratory indications

Selected cases of Allergic Bronchopulmonary Aspergillosis (ABPA) in cystic fibrosis patients, as well as severe childhood interstitial lung disease (CHILD) might be started on IV methylprednisolone (off label uses). The dose for this would be **10mg/kg/day (no maximum dose)** once a day for 3 days. Confirm the dose from the notes / responsible consultant's team, as it may vary dependent on the indication and clinical status of the child / young person.

Gastrointestinal indications

For patients with Inflammatory Bowel Disease the guidelines now suggest a lower dose of 1-1.5mg/kg/day (maximum 60mg). This can be given as a single or divided daily dose (ECCO guidelines for Crohn's Disease and Ulcerative Colitis).

Use of acid suppression

Ensure oral Omeprazole (1mg/kg – round to the nearest 10mg – maximum 40mg) has been given on day of infusion. For respiratory indications, this is not routinely needed for a 3-day course of methylprednisolone

Patient exclusion criteria

- Patients with sepsis, or with clinically apparent infection or abscesses (discuss with consultant).
- Patients who are hypersensitive to methylprednisolone or any other excipients.
- Caution required in patient with active peptic ulcer, pregnancy, epilepsy, diabetes.

Pre infusion check list

1. Check patient's weight and height prior to first dose and update EPMA accordingly
2. Give regular medication including analgesia but **omit oral steroids**.
3. Please confirm if oral steroids were given at home prior to inpatient therapy.
4. Apply Ametop/EMLA cream if desired. At insertion of cannula review if bloods are needed, including varicella zoster titres.
5. Monitor base line observations: pulse, BP, temperature, BM, urinalysis, record on nursing documentation.
6. Clinical review to ensure the patient has no signs of infection or history of recent contact with infection (including chicken pox). If risk of infection likely discuss with the responsible team before giving infusion.

Preparation

1. Calculate the dose required 10-30mg/kg/day (maximum 1000mg) for rheumatology patients, 1-1.5mg/kg/day (maximum 60mg) for Inflammatory Bowel Disease patients and 10 mg/kg/day for respiratory/CF patients
2. Reconstitute each vial as follows using a 21-gauge needle or less:
3. **Solu-Medrone and Beacon methylprednisolone sodium succinate (for other brands consult product information):**
   Reconstitute vials with the water for injections provided. Taking displacement values into account, the final concentrations are:
   40mg vial: 40mg in 1mL
   125mg, 500mg, 1g and 2g vials: 60mg in 1mL.
4. Swab vial top with a 70% alcohol swab and allow to dry.
5. Inject the water against the glass wall of the vial. Do not use the vial if the vacuum is not present.
6. Withdraw prescribed dose and dilute in 100mL sodium chloride 0.9%.
7. Gently mix. Fix additive drug label according to Trust policy.
8. Methylprednisolone sodium succinate infusion should be administered via a sterile giving set. Connect the infusion with a Y-connector and prime giving set with methylprednisolone sodium succinate solution. Infusions must be administered via a volumetric pump.
9. Following reconstitution and dilution the infusion must be started as soon as possible. Do not store any unused portion for further re-use.

10. The infusion is given over 30 minutes for 10 mg/kg and for higher does (for 20-30mg/kg) over at least 2 hours. it is recommendation that there is 50mL NaCl flush at the end

Monitoring

1. The patient should be monitored closely during the infusion period and should stay in ward area for the duration of the infusion. Observations of BP, pulse and temperature must be recorded every 15 minutes during infusion and for 1 hour post infusion. Each urine passed should be tested for glycosuria. Patients must stay in the Jenny Lind department for at least 1 hour after the infusion has finished.
2. Observe the cannula site for extravasation and the infusion for any changes in colour or consistency.
3. In the event of any reaction STOP the infusion and report to medical staff.

Side effects

- Hypotension, hypertension, tachycardia, blurred vision, flushing, sweating, metallic taste in the mouth, glycosuria and mood changes.
- Rarely seizures and psychotic episodes.
- Some children are very lethargic after infusion for a few hours.

Treatment for infusion reactions

- Hypertension / hypotension / tachycardia / blurred vision, flushing, sweating all uncommon – report to responsible physician (SHO/SpR) and stop infusion until seen. The child's BP should be checked against previous results from clinic and against age and sex norm charts. If there is a rise in BP greater than 20mmHg from baseline SpR to decide in conjunction with the consultant the appropriateness of continuing infusion at a reduced rate.
- Bad taste in mouth is common – recommend sucking on mints.
- Pain at infusion site common – slow rate or dilute drug further (500mL).
- If glycosuria occurs, check BM and ketones. Discuss with clinician.

Anaphylaxis - discontinue the infusion and Immediate Medical Attention according to APLS/EPLS guidelines.

- Adrenaline IM
  - Less than 6 months: 100-150 micrograms
  - 6 months to 6 years: 150 micrograms,
  - 6-to 12 years: 300 micrograms,
  - Greater than 12 years: 500 micrograms.
- Sodium Chloride 0.9% 20mL/kg.

NB. Any infusion reaction should be reported to the child's Consultant.

Required blood monitoring

- Before first infusion FBC, U&Es LFTs, Bone group, CRP and ESR and varicella zoster status should be known (bloods taken within the preceding week are acceptable).

After infusion course, liaise with relevant team as to the follow-up blood monitoring required.

Discharge advice

1. The cannula will usually remain in-situ until the patient has completed all three doses of methylprednisolone sodium succinate; pls give patient advice leaflet and separate cannula care leaflet if necessary
2. All patients on methylprednisolone sodium succinate have open access to CAU; ensure PAS completed for open access
3. Ensure patient is given blue steroid card after first infusion.
4. Ensure patient has forms for blood monitoring as required.
5. After final infusion make appropriate follow-up appointment in conjunction with relevant team.
6. **Oral prednisolone** might commence the day after the infusion for some indications– ensure a plan has been made by the relevant team.
7. Ensure that the patient's General Practitioner (GP) is sent a discharge letter (electronic form).
8. If Varicella zoster (VZV) negative advise parent to contact CAU if child has contact with VZV.

Clinical Audit Standards

- Frequency and severity of adverse reactions
- Assessment of efficacy of response
- Timing of administration within guidelines
- Monitoring of administration within guidelines

Summary of development and consultation process undertaken before registration and dissemination.

This guideline has been drafted in conjunction with the paediatric Rheumatology and Gastroenterology team. During its development it has been circulated for comment within the Pharmacy Department, Paediatric Directorate Where appropriate comments have been incorporated into the final version.

Reviewed in 2015 by Paediatric team who determined the guideline remains clinically robust. In 2020 it was confirmed that the document remained current but give a 1 years review as there is expected to be a regional document shortly. In 2021 the respiratory/CF/Gastro team added indications and doses for their patients

Distribution list / dissemination method

CDW
CAU
Buxton
Pharmacy Services
Trust Intranet

References / source documents

BNF for children 2015

BSPAR (British society for paediatric and adolescent rheumatology) guidance

https://www.bspar.org.uk/DocStore/FileLibrary/PDFs/BSPAR%20guidance%20for%20Methylprednisolone%202011.pdf

Immunisation against infectious diseases (green book) DOH online

Consensus guidelines of ECCO/ESPGHAN on the medical management of Pediatric Crohn's Disease

F.M. Ruemmele et al, *J crohn's and Colitis* (2014) **8**, 1179-1207

Management of Pediatric Ulcerative Colitis: joint ECCO and ESPGHAN evidence based consensus guidelines

Turner D et al *J Pediatr Gastroenterol Nutr*. 2012 Sep; **55** (3): 340-61

Pulse methylprednisolone in allergic bronchopulmonary aspergillosis exacerbations

Inderpaul Singh Sehgal, Ritesh Agarwal European Respiratory Review Mar 2014, 23 (131) 149-152

Clinical guidelines: Care of children with cystic fibrosis, 202. Royal Brompton Hospital https://www.rbht.nhs.uk/childrencf

Bush A, Cunningham S, de Blic J, et al. European protocols for the diagnosis and initial treatment of interstitial lung disease in children. Thorax 2015; **70**: 1078–1084