Corticosteroid dosing for patients with ANCA-Associated Vasculitis (AAV)

Background

Since the 1970s, therapy consisting of a combination of oral glucocorticoids (1mg/kg/day; maximum daily dose 80mg) in combination with immunosuppressive drugs has been used in the treatment of AAV.1 This is often combined with several doses (“pulses”) of intravenous Methylprednisolone (e.g. 500mg-1g daily IV for 3 days) in patients with severe disease.2

Low dose glucocorticoids in combination with azathioprine, rituximab, methotrexate or mycophenolate mofetil are recommended for remission maintenance in AAV.1

Laboratory data suggest lower glucocorticoid doses may mitigate their toxicity while maintaining anti-inflammatory effects.3 Infections in AAV are most common in the first 6 months of treatment when glucocorticoid doses are highest.4 Infection rates fall in parallel with decreasing glucocorticoid dose despite the maintenance of constant immunosuppression over time.3

PEXIVAS is a randomized clinical trial evaluating adjunctive plasma exchange and two oral glucocorticoid regimens in severe AAV. The reduced-dose glucocorticoid regimen of the PEXIVAS study is outlined in the table below. This regimen provides approximately 55% of the standard dose regimen used in the clinical trial over the first six months. It was preceded by a total IV methylprednisolone dose of between 1 and 3 grams.3

The dose of IV methylprednisolone, if prescribed, should be confirmed by the consultant.

**References**

1. EULAR/EDTA recommendations for the management of ANCA-associated vasculitis. Yates *et al.* Ann Rheum Dis 2016;75:1583-1594.
2. Gopaluni S, Jayne D. Clinical Trials in Vasculitis. Curr Treat Options in Rheum 2016;2:161-177.
3. Walsh M, Merkel P, Au Peh C, *et al.* Plasma exchange and glucocorticoid dosing in the treatment of anti-neutrophil cytoplasm antibody associated vasculitis (PEXIVAS): protocol for a randomized controlled trial. Trials 2013;14:73.
4. Jayne D, Gaskin G, Rasmussen N *et al.* European Vasculitis Study Group: Randomized trial of plasma exchange or high-dosage methylprednisolone as adjunctive therapy for severe renal vasculitis. J Am Soc Nephrol 2007;18:2180-2188.

**Reduced dose glucocorticoid regimen (PEXIVAS regimen)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Week Number(s)** | **Oral Dose Prednisolone based on patient weight** | | |
|  | **<50kg** | **50-75kg** | **>75kg** |
| 1 | 50mg once daily | 60mg once daily | 75mg once daily |
| 2 | 25mg once daily | 30mg once daily | 40mg once daily |
| 3-4 | 20mg once daily | 25mg once daily | 30mg once daily |
| 5-6 | 15mg once daily | 20mg once daily | 25mg once daily |
| 7-8 | 12.5mg once daily | 15mg once daily | 20mg once daily |
| 9-10 | 10mg once daily | 12.5mg once daily | 15mg once daily |
| 11-12 | 7.5mg once daily | 10mg once daily | 12.5mg once daily |
| 13-14 | 6mg once daily | 7.5mg once daily | 10mg once daily |
| 15-16 | 5mg once daily | 5mg once daily | 7.5mg once daily |
| 17-18 | 5mg once daily | 5mg once daily | 7.5mg once daily |
| 19-52 | 5mg once daily | 5mg once daily | 5mg once daily |
| After week 52 | As per consultant decision | | |

**Prescriber Instructions for completion of Proforma:**

1. If a patient completes a week or weeks of steroid treatment as an in-patient, write “completed as in-patient” across the “Week”, “Date” and “Prednisolone Dose” section of the proforma.
2. After initial dosing, any departures from a standard wean will entail reverting to standard prescriptions as done currently. Document in the notes that the proforma has been suspended and document the revised dose in the notes.

A carbon copy of the prescription should be filed in the patient’s notes so it is transparent there has been a change, as per hospital policy.

1. A standard prescription for 5mg once daily orally can be written after week 26.
2. A copy of the completed pro-forma needs to be filed in the patient’s notes.

**Proforma Oral Prednisolone Prescription – AAV patients**

**Patient Addressograph**

|  |  |
| --- | --- |
| **Patient Weight:** | **Date weight recorded:** |
| **Allergy Status:** | |
| **Prescribing as per PEXIVAS regimen: Yes □ No □** | |
| **If “No” please detail reason(s) for variation from regimen:** | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Weight Category (1) <50kg □ (2) 50-75kg □ (3) >75kg □** | | | | | |
| **Week Number** | **Date** | **Prednisolone Dose** | **Week Number** | **Date** | **Prednisolone Dose** |
| **1** |  |  | **14** |  |  |
| **2** |  |  | **15** |  |  |
| **3** |  |  | **16** |  |  |
| **4** |  |  | **17** |  |  |
| **5** |  |  | **18** |  |  |
| **6** |  |  | **19** |  |  |
| **7** |  |  | **20** |  |  |
| **8** |  |  | **21** |  |  |
| **9** |  |  | **22** |  |  |
| **10** |  |  | **23** |  |  |
| **11** |  |  | **24** |  |  |
| **12** |  |  | **25** |  |  |
| **13** |  |  | **26** |  |  |

|  |  |  |
| --- | --- | --- |
| **Prescriber Signature:** |  | |
| **IMC Number:** |  | **Date of Prescription:** |
|  | | |
| **Name of Consultant** |  | |