Formulário de acesso a dados do Registo Nacional de Doentes Reumáticos

(Reuma.pt) da SPR, 2014-2016

1. Title

Reuma.pt/ Vasculitis: The Portuguese Vasculitis Register

2. Background

The vasculitides are a group of relatively uncommon and complex diseases with different manifestations and outcomes, often challenging to most clinicians. [1]

The Rheumatic Diseases Portuguese Register, Reuma.pt, was created in June 2008 [2] and up until September 2014 included specific protocols for seven different groups of rheumatic diseases.

The increasing need for a better understanding of vasculitis, the growing research dedicated to these diseases, the recent approved use for biologic treatment in certain types of vasculitis, and mainly the necessity to know the characteristics of the Portuguese patients with vasculitis attending the different rheumatology centres across the country led to the creation of a new protocol exclusively dedicated to vasculitis – Reuma.pt/ Vasculitis [3]. This electronic clinical record aims to improve the monitoring and clinical care of Portuguese patients with vasculitis. It is intended to allow the generation of a robust database of patients with systemic vasculitis and an archive of longitudinal clinical data able to define the clinical course of these diseases over time.

Through collaboration between the Sociedade Portuguesa de Reumatologia and the Nuffield Orthopaedic Centre (Prof. Luqmani), specific classification and assessment tools for patients with vasculitis were included in Reuma.pt/Vasculitis. These integrated tools are also present in different research registries (e.g. UKIVAS) to allow comparison of the various vasculitis features between countries - Benchmarking.

In October 2014 the Reuma.pt/vasculitis was officially launched, 12 different rheumatology centres agreed to participate in entering data. By mid-January 285 patients with vasculitis were already registered.

3. Objectives

Primary objectives
1. To describe the structure and functioning of Reuma.pt/Vasculitis.
2. To characterize the Portuguese patients with the diagnosis of vasculitis according to the Chapel Hill nomenclature registered in Reuma.pt/Vasculitis.

Secondary objectives
1. To assess the number and disease duration of the patients with vasculitis secondary to Rheumatoid Arthritis registered in Reuma.pt/Rheumatoid Arthritis with or without biologics.
2. To assess the number and disease duration of the patients with vasculitis secondary to Systemic Lupus Erythematosus (SLE) registered in Reuma.pt/SLE.
3. To compare the data dictionaries from Reuma.pt/vasculitis and UKIVAS and the most frequent diagnoses registered in both databases.

4. Inclusion/exclusion criteria

For the primary objectives we will analyse all patients recorded in Reuma.pt/vasculitis up to January 2015 with a selected diagnosis within the Chapel Hill 2012 nomenclature. Patients with missing diagnosis will be excluded from analysis. Additionally, within each category of the protocol we will exclude patients with missing data from analysis. At this point we will include for evaluation all patients bellow 18 years registered in Reuma.pt/Vasculitis given a specific protocol for paediatric patients with vasculitis is still in development.

For the secondary objectives we will analyse all patients registered in Reuma.pt/Rheumatoid Arthritis with or without biologics, Reuma.pt/SLE and UKIVAS up to January 2015.

5. Methodology

5.1 Type of study

Cross sectional study of the data collected up to the last visit of each patient registered in Reuma.pt/Vasculitis, Reuma.pt/Rheumatoid Arthritis with or without biologics and Reuma.pt/SLE in January 2015. Cross sectional analysis of all patients registered in UKIVAS up to January 2015.

5.2 Type of analysis

a) Analysis performed in patients registered in Reuma.pt/vasculitis: Descriptive analysis of the number of patients registered per centre; number of visits per patient; demographics; disease duration; delay in diagnosis; diagnosis according to the Chapel nomenclature; classification/diagnostic criteria of the most common types of vasculitis registered; co-morbidities; smoking/alcohol habits; specific medications and drugs (known to be associated with vasculitis); immunology and genetics; imaging/biopsies of the most common diagnosis; treatment with classic and biologic immunosuppressive treatment; and adverse-events.

Regarding the disease assessment tools, the mean five factor scores of patients with granulomatosis with polyangiitis (GPA), microscopic polyangiitis (MPA), eosinophilic granulomatosis with polyangiitis (EGPA) and polyarteritis nodosa (PAN) will be calculated, as well as the mean cardiovascular risk of patients with MPA and GPA. In addition, the mean scores of the BVAS assessed at first visit and VDI at last visit of all vasculitis diagnosis will be analysed.

b) Analysis performed in patients registered in Reuma.pt/Rheumatoid Arthritis with or without biologics and Reuma.pt/SLE: Calculation of the frequency that the disease manifestation "vasculitis" was selected per patient registered in each protocol with calculation of disease duration in those selected cases.

c) Analysis performed in patients registered in UKIVAS: Comparison of the data dictionary of UKIVAS with Reuma.pt/vasculitis; descriptive analysis of the centres inserting patients, demographics and diagnosis; and assessment of the feasibility of combining data from both registries.

6. Expected limitations

Limitations characteristic of retrospective studies, particularly underreporting or missing data

7. Calendar of tasks

Data collection of patients inserted until mid-January 2015.

Presentation of the results in the Vasculitis Workshop (31 January 201)

Abstract submission to SPR Simpósio 2015 (deadline 7 February 2015)

Submit as publication to ACTA Reumatologia Portuguesa (April/ June 2015)

7. Team

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7. <u>Centro Hospitalar do Algarve:</u> Graça Sequeira
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UKIVAS: Jan Sznajd et al

8. Disclosure statement

The authors have declared no conflicts of interest.

9. References

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