Over the last 2 decades rituximab (RTX) has been widely used, albeit off-label, in primary Sjögren's syndrome (pSS). Several studies reported that B-lymphocyte depletion with RTX is effective in this disease not only by reducing disease activity but also by affecting the inflammation and the lymphoid organization that occur in target tissues. With the recent release of several RTX biosimilars (bRTX) on the market, the demonstration of their interchangeability of oRTX and bRTX in pSS.

**Methods:**

To compare efficacy and safety of oRTX and bRTX in pSS patients in a real-life setting.

**Background:**

Over the last 2 decades rituximab (RTX) has been widely used, albeit off-label, in primary Sjögren’s syndrome (pSS). Several studies reported that B-lymphocyte depletion with RTX is effective in this disease not only by reducing disease activity but also by affecting the inflammation and the lymphoid organization that occur in target tissues. With the recent release of several RTX biosimilars (bRTX) on the market, the demonstration of their interchangeability with RTX originator (oRTX) is required.

**Objectives:**

To compare efficacy and safety of oRTX and bRTX in pSS patients in a real-life setting.

**Methods:**

Clinical records of pSS patients referring to a tertiary rheumatology clinic were retrospectively evaluated. Patients having received at least 2 courses of either oRTX or bRTX (1000 mg IV infusion, repeated after 2 weeks -1 course- and the course repeated after 24 weeks) with complete data at baseline and after 3, 6, 9 and 12 months of treatment were enrolled.

**Results:**

Seven patients that received oRTX and 7 patients that received bRTX were enrolled. Baseline clinical features, including ESSDAI and ESSPRI were assessed with the EULAR SS disease activity index (ESSDAI) and its clinical version without the biological domain (ClinESSDAI). Patient-reported symptoms were assessed with the EULAR SS Patient Reported Index (ESSPRI).

**Disclosures of Interests:** None declared.

**References:**


---

**AB0369**

**EFFICACY AND SAFETY OF RITUXIMAB ORIGINATOR AND BIOSIMILAR IN PRIMARY SJÖGREN’S SYNDROME IN A REAL-LIFE SETTING**

E. Carubbi1, A. Alunno2, P. Cipriani, V. Pavlych1, C. Di Muzio1, R. Geri1, R. Giacomelli1, 1Rheumatology Unit, University of Udine, Italy, Italy; 2Rheumatology Unit, University of Perugia, Italy

**Background:**

Seven patients that received oRTX and 7 patients that received bRTX were enrolled. Baseline clinical features, including ESSDAI and ESSPRI were similar in the 2 treatment groups. Both compounds significantly reduced ESSDAI and ESSPRI as early as 3 months and no difference between the groups was observed at any time point (Figure 1). Of interest, ESSDAI slowly decreased until month 6 when the most pronounced reduction was observed. Conversely, ESSPRI dropped to its lowest values already at month 3. With regard to safety, at 12 months of follow-up no adverse event was observed in any of the treatment groups.

**Conclusion:**

At 12 months of follow-up, oRTX and bRTX display similar efficacy and safety profiles. The improvement of patient reported outcomes is faster than the improvement of disease activity with both compounds. Our data support interchangeability of oRTX and bRTX in pSS.

**References:**


---

**AB0370**

**SAFETY OF CS20AT04, A HAPLOIDENTICAL ALLOGENIC BONE MARROW-DERIVED MESCENHYMAL STEM CELLS, IN A PHASE 1 STUDY IN LUPUS NEPHRITIS**

C. B. Choi1, T. Y. Lee2, K. S. Kim2, S. C. Bae1, 1Hanyang University Hospital for Rheumatic Diseases, Rheumatology, Seoul, Korea, Rep. of (South Korea); 2Corestem Inc, Seongnam, Korea, Rep. of (South Korea)

**Background:**

Mesenchymal stem cells are known to have immunomodulatory properties and may potentially have therapeutic effect in lupus nephritis. Mesenchymal stem cells form a haploidentical donor are an attractive cell source.

**Objectives:**

To determine the maximum tolerated dose and evaluate the safety and tolerability of CS20AT04, a haploidentical allogeneic bone marrow-derived mesenchymal stem cell, was evaluated in patients with lupus nephritis for safety and tolerability.

**Methods:**

This was a single-arm phase 1 dose-escalation trial of CS20AT04 in adult patients with lupus nephritis (NCT03174987). A 3+3 design was used for dose escalation. The starting dose was 2.0 x 106 cells/kg and was escalated to 3.0 x 106 cells/kg if there do not dose-limiting toxicity. The primary objective was to determine the maximum tolerated dose and evaluate the safety and tolerability at 28 days after the infusion.

**Results:**

Seven patients were enrolled in the study. Patients received CS20AT04 through intravenous infusion. The initial dose of 2.0 x 106 cells/kg was administered for the first 3 patients without any dose limiting toxicity. There was 1 patient who were not administered the full 2.0 x 106 cells/kg dose due to technical error during infusion. The patient did not show dose limiting toxicity, but 1 additional patient was enrolled to have 3 patients who received the full 2.0 x 106 cells/kg dose before escalating to the next level dose. The dose of 3.0 x 106 cells/kg was administered for the next 3 patients without any dose limiting toxicity. Three adverse events were reported (1 diarrhea, 1 toothache, and 1 arthralgia) and were all NCI-CTC grade I events.

**Conclusion:**

CS20AT04 was well tolerated in single dose up to 3.0 x 106 cells/kg in patients with lupus nephritides.

**Acknowledgements:**

This research was supported by a grant of the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HI15C0778).

**Disclosure of Interests:** Chan-Bum Choi: None declared, Tae Yong Lee Shareholder of: Corestem Inc, Employee of: Corestem Inc, Kyung Suk Kim Shareholder of: Corestem Inc, Employee of: Corestem Inc, Sang-Heol Bae: None declared

**References:**

http://ard.bmj.com/content/10.1136/annrheumdis-2020-eular.3287

---

**AB0371**

**HYDROXYCHLOROQUINE AS VIEWED BY LUPUS PATIENTS – WHAT IMPACT FOR DOCTORS?**

A. Cornet1, Z. Osmani2, S. Frankel1 on behalf of LUPUS EUROPE PATIENT ADVISORY NETWORK. 1Lupus Europe, Romford, United Kingdom; 2WLE, Amsterdam, Netherlands

**Background:**

Hydroxychloroquine (HCQ) is recommended for all patients with systemic lupus erythematosus (SLE) and is typically considered as having a good safety profile. Yet, patient organisations observe that concerns about eye impact or ‘allergies to HCQ’ are often raised on social media. This could contribute to the non-adherence, which varies from 3 to 76% in SLE patients depending on assessment method and drug.

**Objectives:**

To understand if/how some patients’ beliefs impact adherence to HCQ treatment.

**Methods:**

In May 2019, LUPUS EUROPE launched a 29 questions on-line survey in 13 languages including questions on HCQ adherence. 2938 responses were analysed. 67.8% (1990 patients) were current HCQ users, 17.8% had stopped using it, 8.1% never had HCQ (6.4% did not respond to this question). 1820 users reported their adherence level. 314 (17.3%) were classified as “low” adherence as they reported missing/forgetting HCQ “always” (1.8%), “more than twice a week” (5.2%) or “once a week” (13.3%).

**Results:**

The prescribed HCQ dose, kidney involvement or duration of treatment (beyond the 1st year) were found to have no impact on low adherence. Similarly, the user belief that HCQ has significant side effects, without experiencing these, was not found to impact adherence (p= .74).

The following factors were associated with better adherence: (p<.0001)

**References:**

1. Lupus Europe, Romford, United Kingdom; 2WLE, Amsterdam, Netherlands

**Disclosure of Interests:**

None declared.