Results: Patients had a variety of retinal testing done, with optical coherence testing most frequent. Table 1 shows the concordance of a test abnormality with the retina expert opinion.

Table 1. – Performance of retinal imaging modalities relative to expert diagnosis

Test	Retinopathy N (%)	No Retinopathy N (%)
Ocular Coherence Tomography (OCT)		
Abnormal	25 (93%)	133 (16%)
Normal	2 (7%)	721 (84%)
Total	27	854
Electroretinogram (ERG)		
Abnormal	15 (100%)	195 (49%)
Normal	0 (0%)	201 (51%)
Total	15	396
Microperimetry (MP1)		
Abnormal	17 (100%)	144 (30%)
Normal	0 (0%)	331 (70%)
Total	17	475
Fundal Autofluorescence (FAF)		
Abnormal	19 (83%)	165 (24%)
Normal	4 (17%)	536 (76%)
Total	23	701

The concordance of the test abnormality with the retina expert opinion showed the following sensitivity and specificity, respectively: OCT 93%, 84%; ERG 100%, 51%; MP1 100%, 70%; and FAF 83%, 76%.

The frequency of retinopathy increased with years of HCQ use [number of retinopathies per total patients (percent frequency)]: 5 years or less, 1/103 (0.97%); 6-10 years, 2/109 (1.83%); 11-15 years, 3/91 (3.30%); 16-20 years, 11/96 (11.46%); and 21 or more years, 6/75 (8.00%).

Conclusion: In agreement with the American Academy of Ophthalmology, OCT appears to be the optimum test for yearly monitoring (2). The frequency of retinopathy was much lower in our prospective study than estimated by the Kaiser-Permanente study. Our data also show the need for ophthalmologists with retinopathy expertise to interpret retina testing, as screening tests are frequently abnormal due to causes other than HCQ retinopathy. Stopping HCQ based on an abnormal test without confirmation from a retinopathy expert could needlessly deprive an SLE patient of an important medication.

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STUDY DESIGN FOR A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF REPOSITORY CORTICOTROPIN INJECTION IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS DESPITE MODERATE-DOSE CORTICOSTEROIDS

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Background: Repository corticotropin injection (RCI) is a complex mixture containing purified porcine pituitary adrenocorticotrophic hormone (ACTH)-

analogue with potential anti-inflammatory and immunomodulatory effects through the melanocortin receptors (MC1R, MC3R-MC5R) and endogenous steroid production. RCI is approved by the US FDA for the treatment of acute exacerbations (ie, disease flares) or as maintenance therapy in patients with systemic lupus erythematosus (SLE). In a pilot study, RCI was well tolerated with improvements in disease activity for lupus patients treated with RCI compared to those who received placebo (Furie et al, 2016).

Objectives: To discuss the design, demographics, and baseline characteristics of a clinical trial evaluating the role of RCI in the treatment of patients with inadequately controlled SLE disease activity.

Methods: This is a multicenter, double-blind, randomized, placebo-controlled, 24-week clinical trial aiming to determine the effect of RCI in reducing disease activity for patients with persistently active SLE despite moderate-dose corticosteroids (CSs). Patients are required to have SLE (≥ 4 of 11 ACR criteria from 1997) and active disease (moderate to severe rash and/or arthritis) despite stable dose CSs ≥ 4 weeks prior to screening (7.5 - 30 mg/day of prednisone or equivalent). Patients are treated with RCI 1 mL (80 U) subcutaneously (SC) or placebo 1 mL, every other day for 4 weeks followed by twice per week for 20 weeks. Randomization is stratified by study site location and prednisone or equivalent dose (≤ 20 and > 20 mg/day). Patients remain on stable doses of CSs through Week 16, with tapering encouraged between Weeks 16 and 24. Efficacy is evaluated using the SLE Responder Index-4 (SRI-4) and changes from baseline in SLE Disease Activity Index-2000 (SLEDAI-2K), British Isles Lupus Assessment Group-2004 (BILAG-2004) scores, and Physician's Global Assessment (PGA). The primary efficacy endpoint is the proportion of SRI-4 responders at Week 16. Secondary and exploratory endpoints include changes in disease activity scores over time, prednisone dose, and biomarkers (ie, complements, autoantibodies, inflammatory, bone turnover).

Results: As of 14 December 2018, 124 patients comprised the intent-to-treat (ITT) population. Target enrollment is 270 patients, of which 162 patients are expected to be randomized at approximately 60 sites globally. Demographic and baseline characteristics (Table) were collected, including circulating lymphocyte profiles (CD19+ B Cells, CD3+ total T cells, and CD4 Treg cells), which are consistent with the pilot study of RCI (Furie et al, 2016).

Characteristic	Patients (ITT Population, N=124)
Age, n, mean (SD)	40.6 (12.5)
Female, n (%)	114 (91.9)
Race, n (%)	
Caucasian	45 (36.3)
African American	15 (12.1)
American Indian or Alaska Native	25 (20.2)
Other	39 (31.3)
Ethnicity, n (%)	
Hispanic or Latino	80 (68.5)
Weight, kg, mean (SD)	73.3 (19.2)
SLEDAI-2K Total Score, mean (SD)	9.8 (3.0)
BILAG Total Score, mean (SD)	88.4 (6.6)
Physician's Global Assessment (100 mm), mean (SD)	62.1 (12.3)
Prednisone or Equivalent Daily Dosage, mg, mean (SD)	11.5 (5.2)
Anti-malarials, n (%)	71 (57.3)
Immunosuppressants, n (%)	73 (58.9)
Bone Turnover Markers	
TRAP, ng/mL, mean (SD)	44.0 (23.4)
CTX-1, ng/mL, mean (SD)	0.347 (0.175)

Conclusion: This on-going study assesses the efficacy and safety of RCI for the treatment of refractory SLE in a racially and ethnically diverse population. The rapid onset of action of RCI allows for a 16-week primary endpoint. Patients enrolled in this trial have moderate or high disease activity (as shown by the mean SLEDAI-2K, BILAG, and PGA) and are likely to provide valuable data on the role of RCI in refractory lupus. Bone turnover markers will further define the safety profile of RCI in lupus.

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