Results: 177 patients were started on HCQ, with most (62%) diagnosed with rheumatoid arthritis (Table). Most patients were female (76%) and a third (35%) were older than 60 years old. 9 patients (5.1%) had impaired renal function. 83 patients (47%) were prescribed an initial daily dose of HCQ >5mg/kg/day. By July 2018 (follow-up duration 6-19 months), 127 patients (71.8%) remained on HCQ and will need baseline eye screening.

The remaining 50 patients (28.2%) stopped HCQ due to inefficacy (7.3%), GI disturbance (3.4%), rash (3.4%).

Table:

Patients prescribed hydroxychloroquine (HCQ) from Jan 2017 to Feb 2018	All indications N=177	Rheumatoid arthritis N=110	Connective tissue disease N=46	Inflammatory osteoarthritis N=21
Median age (interquartile range); years	54 (44-64)	55 (43-66)	54 (38-61)	57 (52-61)
Age >60 years; n (%)	61 (34.5)	42 (38.2)	13 (28.3)	6 (28.6)
Females; n (%)	134 (75.7)	74 (67.3)	41 (89.1)	19 (90.5)
eGFR <50; n (%)	9 (5.1)	4 (3.7)	3 (6.5)	2 (9.5)
Mean height (cm)	165	166	162	164
Mean weight (kg)	77	77	73	84
Mean BMI	29	29	27	32
Dose > 5mg/kg/day absolute body weight; n (%)	83 (46.9)	54 (49.1)	23 (50.0)	6 (28.6)
Proportion of patients still on HCQ by July 2018; n (%)	127 (71.8)	85 (77.3)	33 (71.7)	9 (42.8)
Reason for HCQ cessation; n (%)	G: 6 (3.4) R: 6 (3.4) I: 13 (7.3) O: 22 (12.4) D: 3 (1.7)	G: 3 (2.7) R: 4 (3.6) I: 6 (5.5) O: 2 (1.8)	G: 1 (2.2) R: 2 (4.4) I: 3 (6.6) O: 6 (13.0) D: 1 (2.1)	G: 2 (9.5) R: 0 (0) I: 4 (19.0) O: 6 (28.6) D: 0 (0)

Conclusion: Clinicians need to be cognisant of recent guidelines and adjust HCQ dosing to the recommended 5mg/kg/day. Additional specialist pharmacist input for DED (12-13 extra appointments per month) is required. Almost a third of the patients had stopped HCQ by July 2018, mostly due to side effects and reported inefficacy. However, a large proportion (71%) of HCQ starters remain on the drug by 6-12 months and will need baseline screening. Ophthalmology services can estimate services and capacity required for baseline HCQ screening per annum.

REFERENCE:

- [1] Royal College of Ophthalmology Guideline: Hydroxychloroquine and Chloroquine Retinopathy Screening 2018

Acknowledgement: We would like to thank Lloyds Pharmacy of Salford Royal NHS Foundation Trust for providing the data on HCQ prescribing from Jan 2017 to Feb 2018.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.954

SLE, Sjögren's and APS – treatment

FRI0173 HOW WELL DO CLINICAL TRIALS REPRESENT REAL WORLD LUPUS NEPHRITIS PATIENTS?

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Background: Lupus nephritis (LN) represents a serious manifestation of systemic lupus erythematosus (SLE). LN therapies include glucocorticoids and conventional immunosuppressants as standard of care (SOC) or biological therapies. Rituximab (RTX) is used in some patients but published clinical trials have failed to meet their primary end-points. SLE trials have limitations including stringent eligibility criteria in an attempt to achieve homogeneity, however poor recruitment can lead to early termination as such, clinical trials may not reflect the disease population of interest and outcomes can be difficult to generalise.

Objectives: Our aim was to apply published trial eligibility criteria to patients with LN in a large UK-wide register to quantify how accurately LN clinical trials represent a real-world cohort.

Methods: A literature review of recent major published LN clinical trials was performed (n=6). Inclusion and exclusion criteria common across trials were applied to all patients registered in the BILAG-Biologics Register (BILAG-BR) with active LN, a UK-wide registry of patients with SLE. Active LN was defined as a renal BILAG score A or B. We applied available data to inclusion criteria including ACR/SLICC criteria for SLE diagnosis, positive dsDNA or ANA antibodies and a UPCr>100mg/mmol. Available exclusion criteria were active CNS lupus, a history of hepatitis,

malignancy or CKD 4/5, hypogammaglobulinaemia, and cyclophosphamide use within 30 days of entry or previous B cell therapy within 12 months of entry.

Results: As of July 2018, 259/897 (28.9%) patients in BILAG-BR had active LN. In the RTX and SOC groups, 70/230 (30.4%) and 10/29 (34.5%) respectively did not meet all inclusion criteria (Table 1). Meanwhile 118/230 (51.3%) of RTX patients and 6/29 (20.7%) of SOC patients met one or more exclusion criteria. Overall 131/259 (50.6%) did not satisfy all inclusion and exclusion criteria and thus were ineligible for clinical trial entry. Of those patients deemed ineligible, the RTX patients were younger (median age 36 vs. 49 in SOC group, p=0.653) and the majority were non-Caucasian (n=71/121 (58.7%), p=0.251). The majority of patients in both treatment groups were female (p=0.089). UPCr <100mg/mol (n=35) was the most common inclusion criteria missed whilst the commonest exclusion criteria were concomitant active CNS disease (n=22) and hypogammaglobulinaemia (n=24).

Inclusion criteria	RTX	SOC	p
Does not meet ACR/SLICC criteria for SLE	5	0	0.423
Negative dsDNA/ANA	30	4	0.910
UPCr ≤ 100mg/mmol	35	6	0.743
Total (n)	70	10	
Exclusion criteria	RTX	SOC	p
Active CNS lupus (BILAG A/B)	22	2	0.936
H/o hepatitis B or C	8	0	0.668
CKD 4 or 5	20	2	0.743
H/o malignancy	18	0	0.213
Cyclophosphamide <90 days before entry	13	0	0.189
B cell therapy <1 year before entry	14	0	0.172
Hypogammaglobulinaemia <6 (IgG)	24	2	0.550
Total (n)	118	6	
Total NOT* eligible for clinical trial (n)	131 (50.6%)		0.066

Conclusion: In a large national cohort of active LN we found that 50.6% of patients would not be eligible for clinical trial entry using published entry criteria. This poses significant implications on the study of LN treatment in patients with more severe disease. When designing clinical trials, the stringency of eligibility criteria should be reviewed in order to provide greater representation of the target disease population.

British Isles Lupus Assessment Group Biologics Register

Disclosure of Interests: Sophie Collinson: None declared, Ben Parker Grant/research support from: GSK, Consultant for: AZ, UCB, GSK, Eoghan McCarthy: None declared, Ian N. Bruce Grant/research support from: Genzyme Sanofi, GlaxoSmithKline, Consultant for: AstraZeneca, Eli Lilly, GlaxoSmithKline, ILTOO Pharma, MedImmune, Merck Serono, Speakers bureau: GlaxoSmithKline, UCB Pharma

DOI: 10.1136/annrheumdis-2019-eular.4381

FRI0174 SUBCUTANEOUS DOSING OF THE NOVEL ANTI-CD40 ANTIBODY ISCALIMAB ACHIEVES TARGET DRUG EXPOSURE AND CLINICAL EFFICACY IN PRIMARY SJÖGREN'S SYNDROME; RESULTS OF A PHASE IIA RANDOMISED OPEN LABEL TWO ARM PARALLEL GROUP TRIAL

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Background: Primary Sjögren's syndrome (pSS) is a systemic progressive autoimmune disease characterised by formation of lymphoid structures and germinal centres within glandular tissue. Iscalimab (CFZ533) is a novel monoclonal antibody that potently and selectively blocks CD40, a co-stimulatory pathway receptor important for germinal centre reactions