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OP0204

LUPUS COMPREHENSIVE DISEASE CONTROL IN SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS: APPLICATION OF A NEW INDEX

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Background: The main outcomes in SLE patients management are represented by the remission achievement and chronic damage prevention. Even though activity and damage are intimately connected, to date indices including both these outcomes are not available.

Objectives: In the present study, we aimed at assessing the application of a new index, the Lupus comprehensive disease control (LupusCDC), including disease activity and chronic damage progression.

Methods: We performed a longitudinal analysis, including SLE patients according to ACR 1997 criteria, followed-up in the period between January 2014 and December 2018, and with at least one visit per year. Disease activity was assessed by SLE Disease Activity Index 2000 (SLEDAI-2K) and three different remission levels were evaluated, as reported in Table 1 (1).

Table 1. Remission levels considered in the study (1).

Remission level	Definition
Complete Remission (CR)	No clinical and serological activity (SLEDAI-2K=0) in corticosteroid-free and immunosuppressant-free patients (antimalarials allowed)
Clinical remission off-corticosteroids (CIR-GCoff)	Serological activity with clinical quiescent disease according to SLEDAI-2K in corticosteroid-free patients (stable immunosuppressive therapy and antimalarials allowed)
Clinical remission on-corticosteroids (CIR-GCon)	Clinical quiescent disease according to SLEDAI-2K in patients on prednisone 1–5 mg/day (stable immunosuppressants and antimalarials allowed)

Chronic damage was registered according to SLICC damage index (SDI). All the patients were evaluated at baseline (T0) and every 12 months (T1, T2, T3, T4). At each time-point, we calculated the prevalence of LupusCDC, defined as remission achievement plus absence of chronic damage progression in the previous one year. We calculated this outcome including separately the different remission levels.

Results: According with inclusion criteria, 172 SLE patients were evaluated in the present analysis [M/F 16/156, median age 49 years (IQR 16.7), median disease duration 180 months (IQR 156)]. At first assessment, we observed a mean±SD SDI value of 0.7±1.1. In details, 56 patients (32.5%) showed damage in at least one organ/system and the presence of damage was significantly associated with age ($p<0.0001$, $r=0.3$) and disease duration ($p=0.0003$, $r=0.3$). During the follow-up, we observed a significant increase in SDI values compared with T0 (T1: mean±SD 0.8±1.3, $p<0.0001$; T2: 0.8±1.4, $p<0.0001$; T3: 0.9±1.4 $p=0.0001$; T4: 1.0±1.5 $p<0.0001$).

In figure 1A and 1B we reported the proportion of patients achieving the different levels of remission and LupusCDC, respectively. In particular, the LupusCDC definition including CR was the most frequently detected in all time-points evaluated (T1: 18.0%; T2: 31.9%; T3: 27.9%; T4: 24.4%), with a significant difference at T2 [LupusCDC(CR) versus LupusCDC(CIR-GCoff), $p=0.0002$; LupusCDC(CR) versus LupusCDC(CIR-GCon) $p=0.0002$], T3 [LupusCDC(CR) versus LupusCDC(CIR-GCoff), $p=0.03$; LupusCDC(CR) versus LupusCDC(CIR-GCon)

$p=0.006$], T4 [LupusCDC(CR) versus LupusCDC(CIR-GCon), $p=0.002$]. No significant differences were found when comparing the prevalence of different remission levels and the prevalence of LupusCDC including the corresponding remission.

Conclusion: In the present analysis we proposed for the first time a new index including disease activity and chronic damage, in order to evaluate the proportion of SLE patients reaching a comprehensive disease control. We found that CR is most frequently associated with the absence of damage progression.

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Figure 1. Proportion of patients achieving one of the three levels of remission (A), and of patients reaching LupusCDC according with different remission levels (B).

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OP0205

PHASE I STUDY OF D-0120, A NOVEL URAT1 INHIBITOR IN CLINICAL DEVELOPMENT FOR HYPERURICEMIA AND GOUT

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Background: D-0120 is a novel oral selective uric acid transporter (URAT1) inhibitor being developed for the treatment of hyperuricemia and gout by blocking the reabsorption of uric acid (UA) within the renal proximal tubule, thereby reducing serum uric acid concentrations. As a novel URAT1 inhibitor, D-0120 is anticipated to have more potent serum UA reducing effect than the approved URAT1 inhibitor lesinurad, but with less toxicity and wider therapeutic window. The pharmacological potential of D-0120 for the treatment of hyperuricemia and gout was demonstrated in preclinical studies. The results of the in vitro hURAT1 expressed CHO cell model showed that the inhibitory activity of D-0120 is 150-fold more potent than lesinurad and slightly more potent than verinurad.

Objectives: The purpose of this dose escalation study is to evaluate the safety and tolerability of D-0120 in multiple ascending doses in healthy volunteer, to characterize the pharmacokinetics (PK) of D-0120 and to assess pharmacodynamic (PD) effects and determine the drug-drug interaction (DDI) effect of febuxostat and D-0120 in healthy volunteers.

Methods: This is a randomized, double blind, multiple ascending doses Phase I study of D-0120 in healthy volunteers conducted at one site. Thirty-two healthy eligible volunteers with serum uric acid level ≥ 4.5 mg/dL but within normal range at screening were enrolled and dosed with D-0120 within 4 different single agent cohorts for a period of 7 days. Each cohort had 8 subjects randomized at 3:1 ratio for D-0120:placebo. A fifth cohort of 8 healthy eligible volunteers were enrolled and dosed with 5 mg of D-0120 in combination with 40 mg of febuxostat over a period of 9 days. Evaluation of safety, PK and PD was conducted at various timepoints while the patients were in