Impact of Therapeutic Drug Monitoring of Mycophenolate Mofetil in Patients with Lupus Nephritis: A Randomized Clinical Trial

29/01/2026

Study Variables

a) Sociodemographic aspects: Age, sex, educational level, skin color, and race.

b) Clinical aspects: Disease duration (days), comorbidities and disease domains (constitutional, hematologic, cutaneous, articular, neurological, renal, antiphospholipid antibodies, complement, serosal involvement, and highly specific antibodies).

Additional variables include number of hospitalizations and laboratory tests such as: complete blood count, AST, ALT, urea, creatinine, fasting glucose, glycated hemoglobin, lipid profile and cardiovascular risk, urinalysis (type 1) and urinary sediment, antinuclear antibody (ANA), anti-La/SSB, anti-Ro/SSA, anti-dsDNA antibodies, serum complement levels (C3 and C4), protein excretion quantification in urine (24-hour proteinuria), 24-hour and spot UPCR, cytokines (TNF-α, IL-6, IL-12, IL-10), C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), hemostatic markers (D-dimer, prothrombin activity time – PT, activated partial thromboplastin time – aPTT, fibrinogen), and albumin.

c) Pharmacotherapeutic aspects: Medications in use, dosage, and route of administration will be documented at recruitment and throughout the study, including drug interactions that may impact MPA serum levels.

d) Serum MPA measurement: Trough MPA levels (C0) and MMF dose adjustments.

Data Collection

Data will be collected from institutional and primary sources, including electronic medical records from HU-UFMA through the Hospital University Management Application (AGHUx) and interviews with participants with lupus nephritis (LN) at the rheumatology outpatient clinic of HU-UFMA, or via telemedicine if necessary.

For each participant included in the study, the following variables will be collected: identification and sociodemographic data (age in years, gender, educational level, gross income, race/ethnicity, and marital status), medication therapy, diagnosed morbidities and comorbidities, laboratory and pathological test results, clinical data (disease symptomatology), and the number of hospitalizations related to lupus nephritis using a standardized form developed by the researcher (appendix).

Regarding the pharmacist's interventions/recommendations, the following data will be collected: drug-related problem (DRP), intervention performed, time point of the intervention (T1, T2, T3, T4, and T5), and the medical team's adherence to the pharmaceutical intervention.

Statistical Analysis Plan (SAP)

The primary analysis will be conducted using the intention-to-treat (ITT) approach. The proportion of patients achieving renal remission at 12 months will be compared between groups using the chi-square test or Fisher's exact test, as appropriate. A logistic regression analysis will be performed to estimate the adjusted odds ratio, controlling for age, nephritic and nephrotic syndrome, and baseline MMF dose.

MPA concentrations will be evaluated using descriptive statistics and between-group comparison tests (Student's *t* test or Mann–Whitney test). Additional analyses, such as survival models and mixed-effects models, may be conducted on an exploratory basis, depending on the completeness and volume of the data.

All analyses will be performed using STATA and JASP software, adopting a significance level of 5% and 95% confidence intervals.