Baseline characteristics of participants in the MYCOHYPE study: the first randomized controlled trial of mycophenolate mofetil in fibrotic HP

Background: Prednisolone (PRED) and mycophenolate mofetil (MMF) are used to treat fibrotic hypersensitivity pneumonitis (fHP). No randomized controlled trial (RCT) has tested PRED+MMF combination against PRED monotherapy.

Methods: We have initiated an investigator-initiated, multicenter, open-label, parallel-group RCT (MYCOHYPE) in November 2022. Consecutive subjects with fHP are randomised (1:1) to receive either PRED monotherapy or PRED+MMF combination for 52 weeks. All outcomes are assessed at 52 weeks. The primary outcome is the difference in the annual rate of decline in forced vital capacity (FVC) between the study groups. The planned sample size is a minimum of 144 subjects. The study is anticipated to be completed in mid-2026. We analyzed the baseline characteristics of the first 100 subjects included in the study.

Results: Fifty-one (71% women) and 49 subjects (59% women) were randomized to PRED and PRED+MMF groups, respectively. The mean±standard deviation (SD) age (years) in PRED group is 53.2±9.9 compared to 49.7±10.9 in PRED+MMF group. The baseline FVC (%predicted) is 1.71 liters (61.5%) and 1.65 liters (56.7) in the respective groups. Computed tomography of the chest suggests patterns typical, compatible, and indeterminate for fHP in 54, 27, and 19 subjects, respectively. Twenty-six subjects have HP suggested or confirmed in lung biopsy. None of the baseline characteristics differ between the study subjects.

Conclusions: Baseline characteristics of subjects of first 100 subjects do not differ between the study groups in this RCT comparing PRED monotherapy with PRED+MMF combination therapy in fHP (NCT05626387).