

# De Novo Donor-Specific HLA Antibodies after Steroid Withdrawal in Kidney Transplant Recipients: a Prospective, Randomized, Controlled, Parallel Group Study. Preliminary results

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## INTRODUCTION

Steroids represent one of the mainstays of immunosuppression after kidney transplant (KT). Steroid withdrawal reduces metabolic and cardiovascular complications, but whether it increases the risk of acute rejection and the generation of donor-specific anti-HLA antibodies (DSA) is currently undetermined.

## RESULTS

So far, 82 patients have been randomized (42 group A vs 40 group B), with no significant differences in the clinical and demographic characteristics between the groups.

Intermediate analysis at the first year post-KT:

- 1. DSA:** no significant differences in the formation of DSA (0% vs. 0%) after randomization.
- 2. Rejection:** no rejection in those patients in whom prednisone was withdrawn after randomization.
- 3. Renal function:** 1.4±0.4 vs. 1.5±0.4 mg/dL, P=0.435.
- 4. HbA1c levels:** 6.3±1.4 vs. 5.8±0.8%, P=0.290.

**Table 1.**

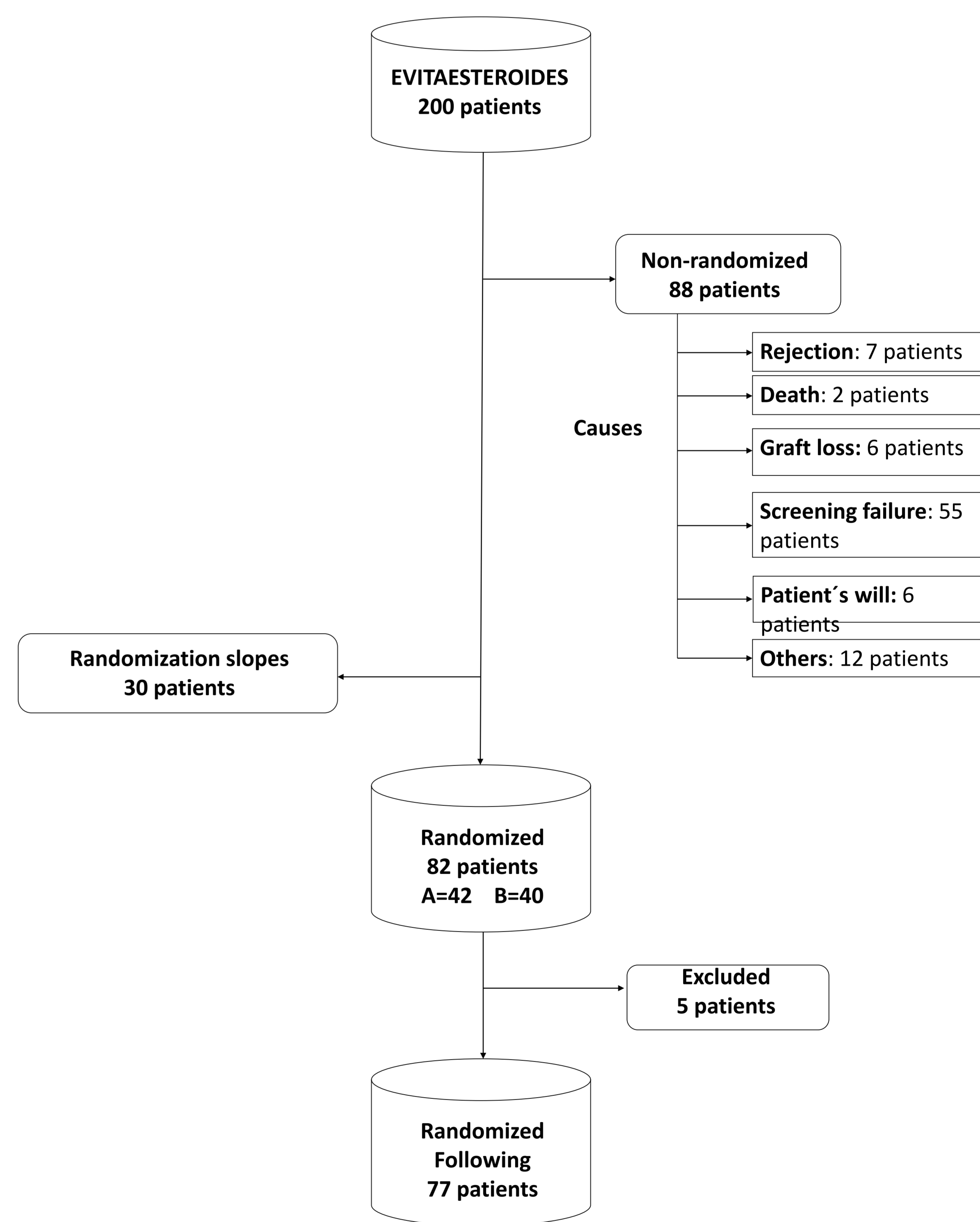
	Group A n=17	Group B n=18	p
Age (years)	55.5±9.8	53.8±13.9	0.523
Gender (M)%	72.5	67.5	0.626
DGF (%)	26.2	30.8	0.648
Blood transfusions (%)	10.8	18.2	0.499
Induction treatment %	95.1	89.5	0.420
<b>3 Months</b>			
•BMI (kg/m <sup>2</sup> )	27.1±4.2	25.5±3.7	0.171
•Creatinine (mg/dL)	1.4±0.4	1.5±0.5	0.092
•HbA1c levels %	6.3±1.5	5.8±0.9	0.180
•Doses TAC (mg)	6.8±3.8	7.4±3.3	0.467
•TAC levels (ng/mL)	9.9±2.7	9.1±2.4	0.231
<b>12 Months</b>			
•BMI (kg/m <sup>2</sup> )	28.5±4.2	25.2±3.0	0.036
•Creatinine (mg/dL)	1.4±0.4	1.5±0.4	0.435
•HbA1c levels%	6.3±1.4	5.8±0.8	0.290
•Doses TAC (mg)	4.4±2.0	6.1±2.4	0.031
•TAC levels (ng/mL)	8.3±2.2	8.4±1.5	0.813
•DMPT %	26.4	0	0,100
•DM %	29.4	23.5	0.697

DGF: delayed graft function; BMI: Body Mass Index; TaC: Tacrolimus; DMPT: Diabetes mellitus post transplant; DM: Diabetes mellitus.

## MATERIAL AND METHODS

- Controlled clinical trial EVITAESTEROIDES(NCT02284464).
- Patients: 200 KT patients with low immunological risk.
- Randomized at 3 months post-KT:
  - Group A: steroids, TAC and MMF.
  - Group B: steroid withdrawal at the third post-KT month.
- Aim: To compare the incidence of de novo DSA, determined by Luminex Mixed and Luminex Single Antigen (One Lambda®), and its impact on graft histology in patients with steroid withdrawal at 3 months post-KT (Group B) versus patients who continue to receive conventional triple immunosuppression (Group A).
- Protocol Biopsy: at 3 months post-KT.

**Figure 1. Clinical Trial Flowchart**



## CONCLUSION

The preliminary results show that steroid withdrawal at 3 months post-KT seems safe when assessing the appearance of rejection and formation of DSA compared to patients who continued to receive conventional triple immunosuppression.