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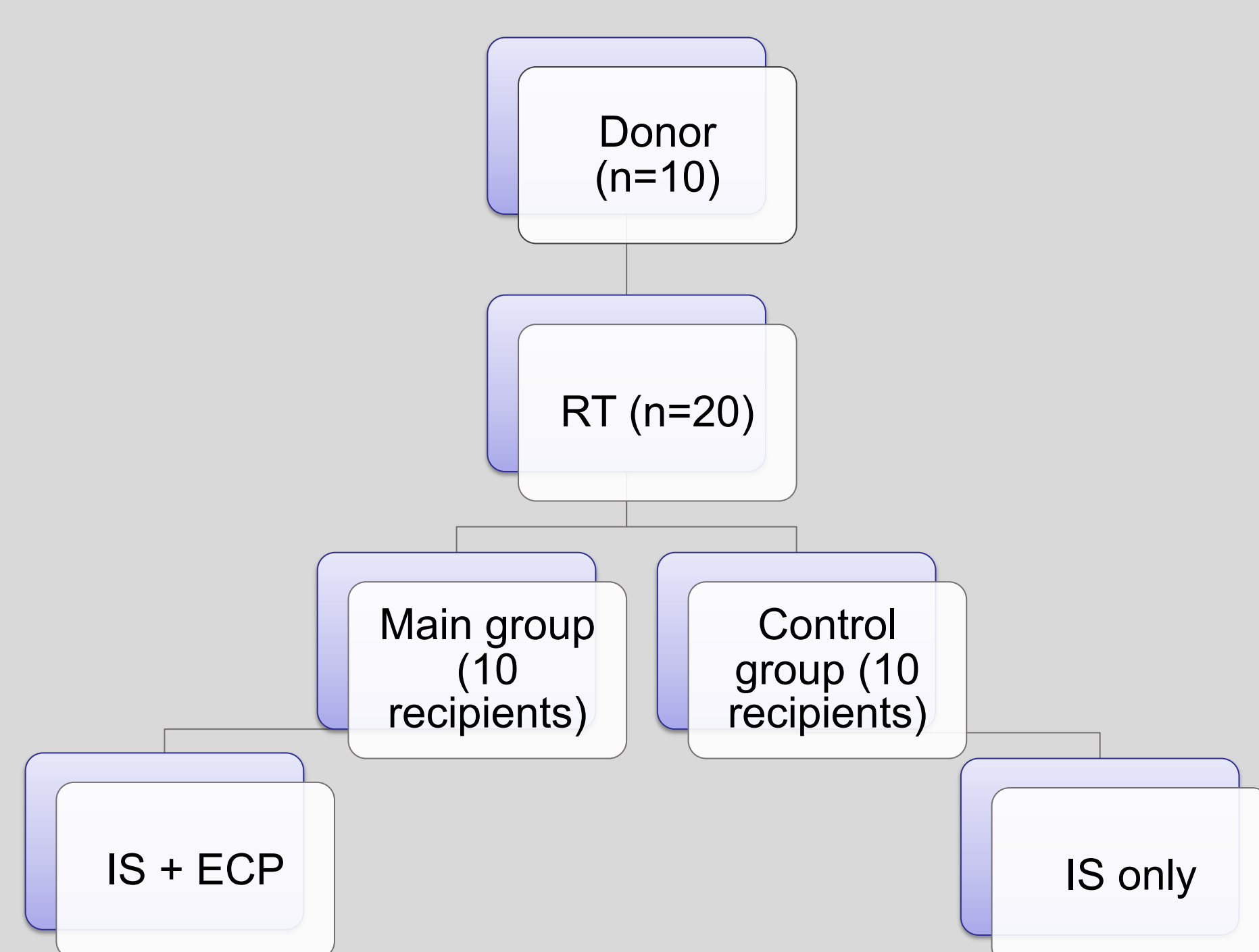
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## INTRODUCTION

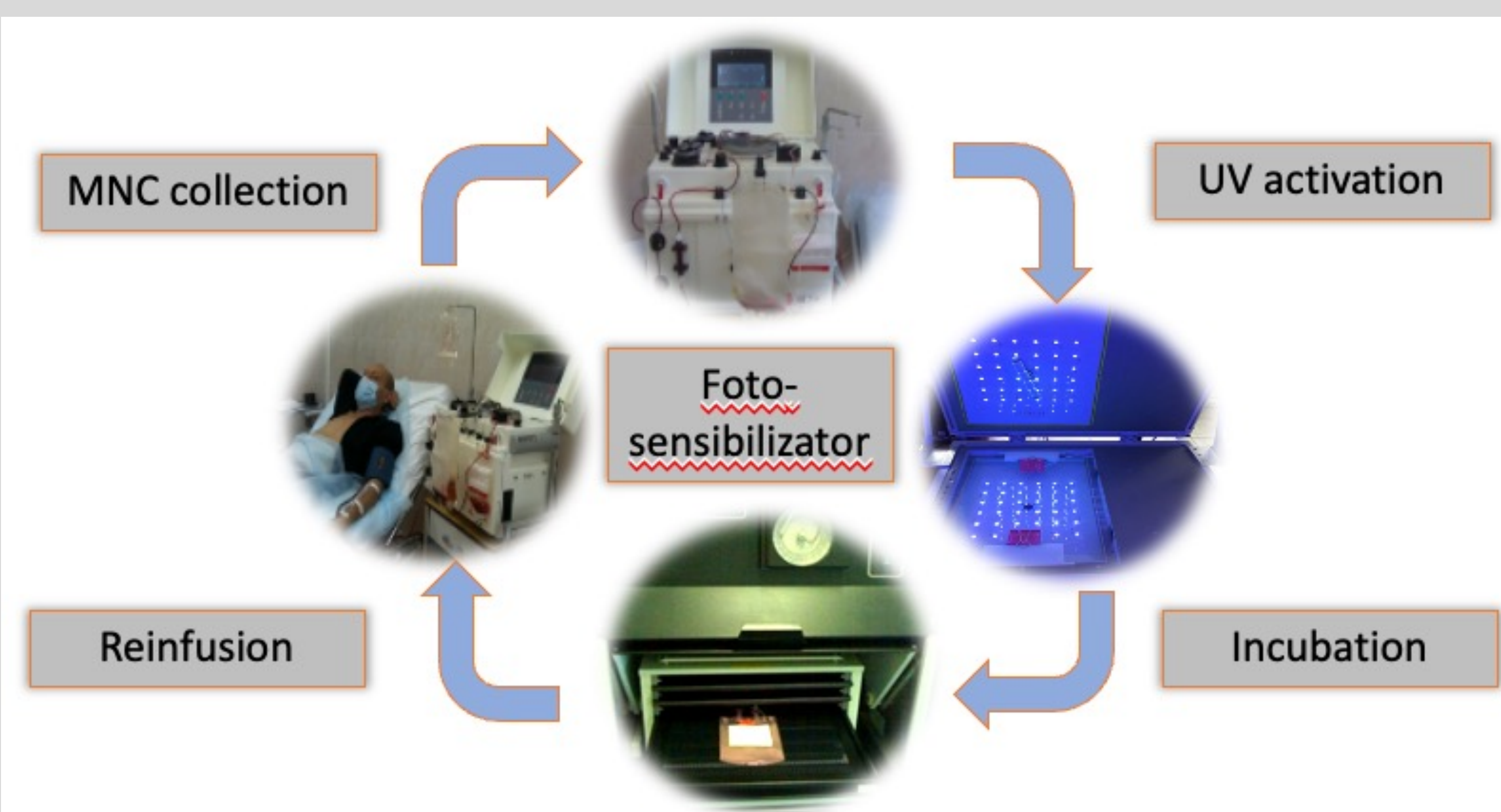
Infectious complications are the second cause of death in kidney transplant recipients [Gamal M. et al., 2022; Agrawal A. et al., 2022; van Delden C. et al., 2020; AwanAA et al., 2018]. The results of renal transplantation (RT) in recent days are associated with individualized immunosuppression strategies of immune tolerance to the graft [BauerAC et al., 2020]. Extracorporeal photopheresis (ECP) repeatedly proved its efficiency for the prevention and treatment of acute renal graft rejection with a decrease in complications associated with immunosuppression [Xipell M. et al., 2021; Augusto JF et al., 2021]. The aim of this study was to evaluate the influence of ECP on the risk of infective complications after KT.

## METHODS

An open cohort randomized study was conducted with the participation of 20 renal allograft recipients who received paired kidneys from 10 donors. In the intervention group all patients received standard immunosuppression therapy (tacrolimus, mycophenolate, prednisone) and 10-15 sessions of ECP during first 6 months after RT. In the control group only the immunosuppression therapy was given. The follow-up period ranged from 2 to 7 years, an average  $4.5 \pm 2.0$  years.

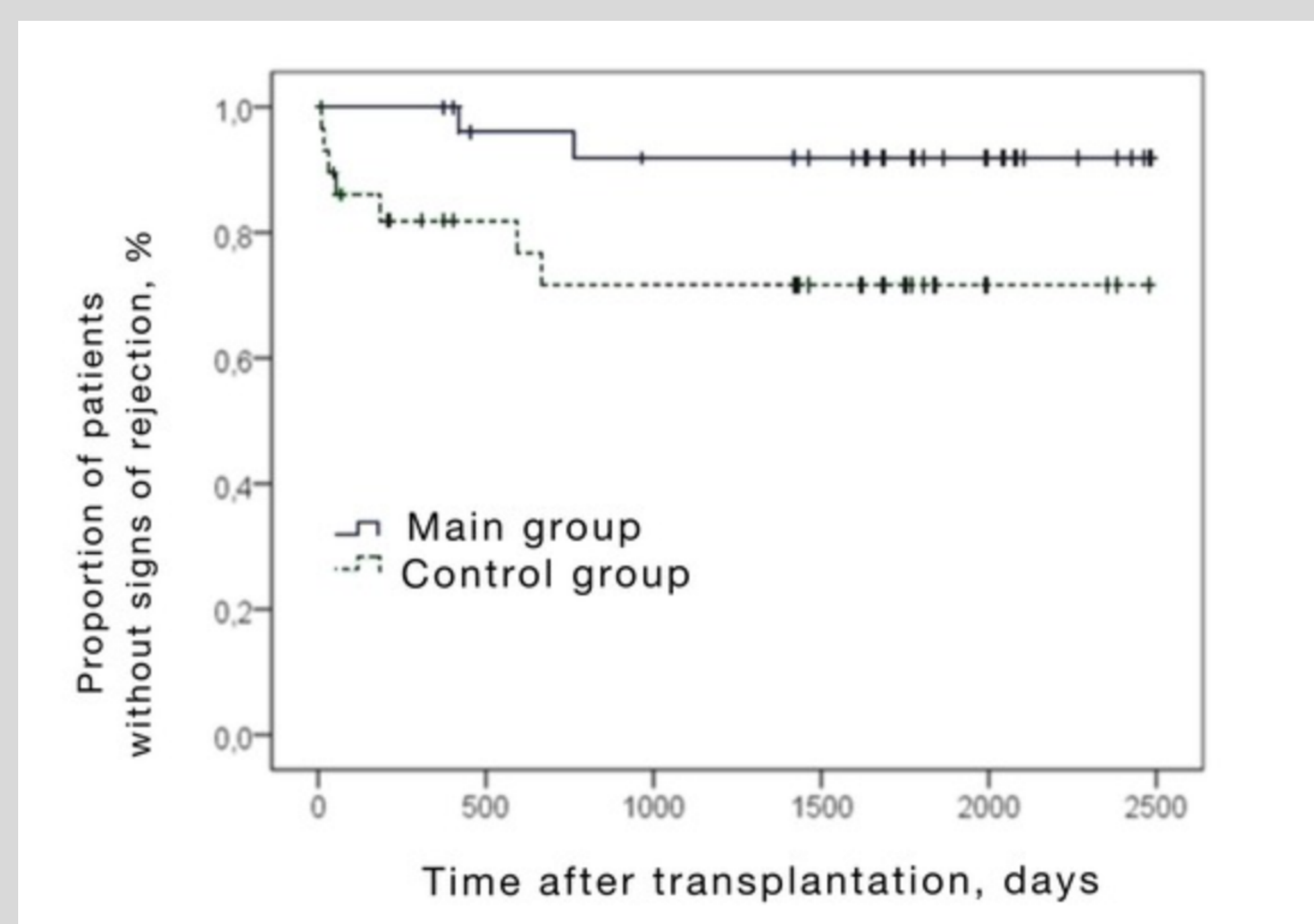


The technique consists of the preliminary medication of a photosensitizer, the separation and accumulation of mononuclear cells by the Haemonetics MCS+, which are then exposed to ultraviolet exposure at a wavelength of 320–400 nm with a total exposure dose of 0.8-1.2 J/cm<sup>2</sup>, and after 90 minutes of the incubation period in a temperature of 37 °C, they are reinfused to the patient.



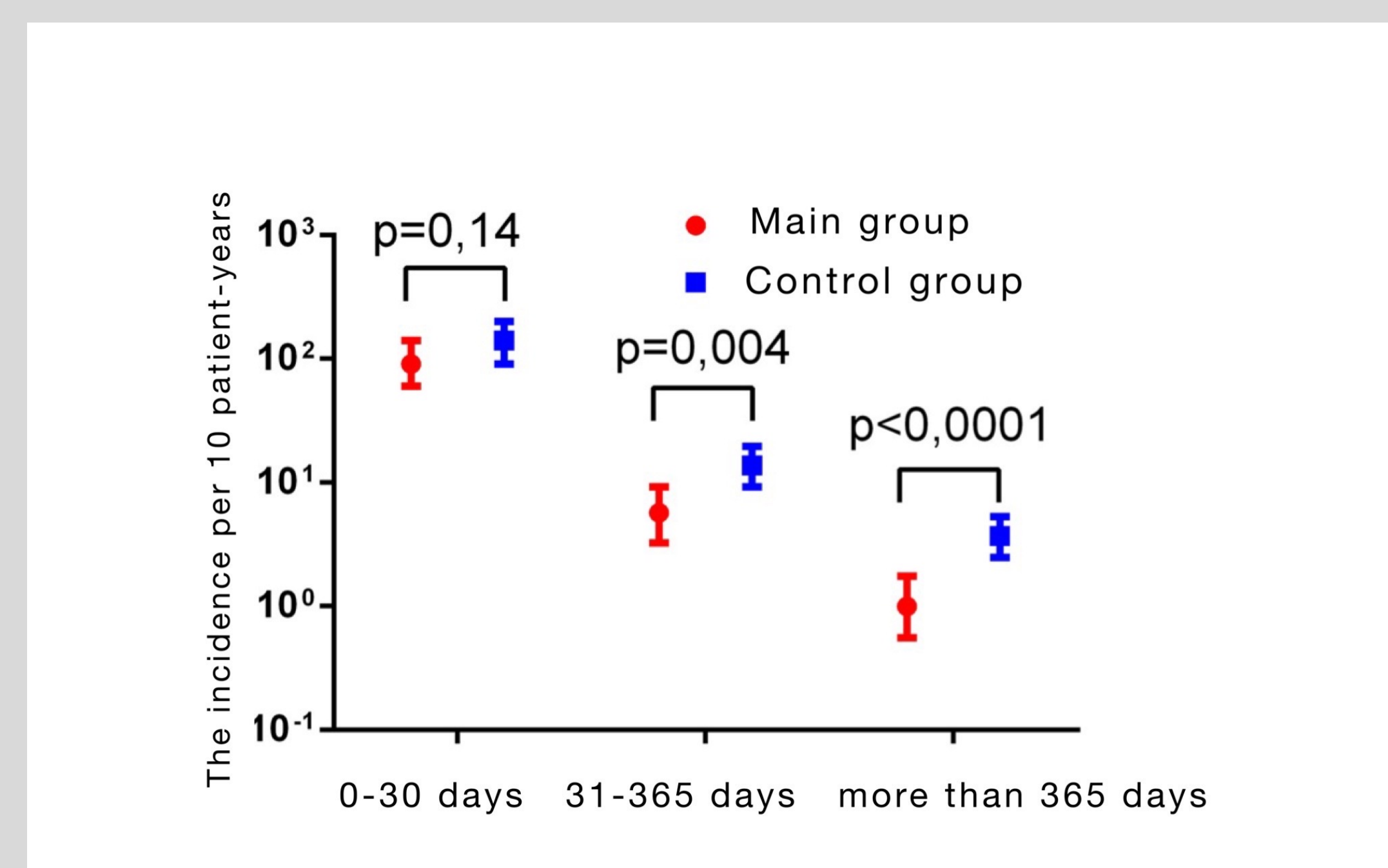
## RESULTS

The risk of rejection in the main group was significantly lower than in the comparison group: IRR 0.2509 (95% CI 0.05386; 0.9167),  $p=0.0358$ . Event-free survival (before the first rejection crisis) was significantly higher in the main group (Log Rank  $p=0.037$ ; Breslow  $p=0.025$ ).



During the first month after transplantation the incidence in the main group was 9.717 (95% CI 6.224; 14.46) per 1 patient-year. In the comparison group - 14.41 (95% CI 9.976; 20.13). The risk of infectious complications 1 month after transplantation in the main group was slightly less than in the comparison group: IRR 0.6761 (95% CI 0.3964; 1.139),  $p=0.14$ . In the period from 31-365 days the incidence in the main group was 5.682 (95% CI 3.246; 9.227) and in the comparison group - 13.72 (95% CI 9.258; 19.59) per 10 patient-years, the risk of infectious complications in the main group was less than in the comparison group: IRR 0.4139 (95% CI 0.2206; 0.7546),  $p=0.00369$ . In the third period of more than 1 year of follow-up the incidence in the main group was 9.993 (95% CI 5.518; 17.46), and in the comparison group - 37.08 (95% CI 24.83; 53.26) per 100 patient-years. Thus, the risk of infectious complications in the main group was less than in the comparison group: IRR 0.2695 (95% CI 0.1327; 0.5211),  $p<0.0001$ .

The frequency of infections in both groups decreases exponentially as the postoperative period increases, but over the entire follow-up period, the incidence in the main group was 4.299 (95% CI 3.21; 5.637) and in the comparison group - 11.06 (95% CI 8.923; 11.06) per 10 patient-years. The risk of clinically meaningful infection was significantly lower in the intervention group than in the control group: IRR 0.3888 (95% CI 0.2754; 0.5445;  $p<0.0001$ ). 6-year survival in the intervention group was 100% to 82.8% in the control group (95% CI 51.6; 93.16).



## CONCLUSIONS

The risk of infections is largely determined by the immunosuppressive drug load, so we believe that this difference between groups is due to some decrease in the concentration of tacrolimus in the main group. However, it is obvious that the prophylactic use of the photopheresis allows to decrease the risk of infective complications after RT.