

# Reduced Immunosuppression in Older Renal Transplant Recipients With Trugraf®/TRAC Monitoring (RIOT Trial): A Prospective, Randomized, Multicenter Trial.

NCT06568549

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 4
<b>Sponsor</b>	Mayo Clinic
<b>Enrollment</b>	350 participants

## Key Eligibility Criteria

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### Inclusion (4)

- Solitary kidney transplant recipient  $\geq 55$  years of age. At most 1 prior solitary kidney transplant.
- No other solid organ transplant though recipients of autologous stem cell transplants are eligible.
- HIV negative.
- Subjects must be on tacrolimus and mycophenolate mofetil or Myfortic at the time of consent. Prednisone at the time of consent is optional and is per local standard of care. Patients randomized to MMF withdrawal will be placed on prednisone 5mg/d at 4 months. Use of other immunosuppression medications for maintenance (cyclosporine, azathioprine, belatacept, sirolimus) is excluded.

### Exclusion (7)

- The results of the most recent DSA testing indicate DSA with an MFI  $\geq 2000$ .
  - The results of the most recent cPRA testing indicate cPRA is above  $\geq 80\%$  (based on MFI  $\geq 2000$ ).
  - Acute rejection episode either clinical or on biopsy (greater than borderline). Subjects must not experience any type of rejection episodes from the time of transplant and must not show any signs of rejection (Cellular or Antibody mediated rejection, excluding borderline) at their 4-month biopsy (If obtained per standard of care). Subjects experiencing rejection will not be eligible for randomization and MMF withdrawal.
  - De novo DSA
  - Subjects who are not on tacrolimus at the time of randomization will be placed in the non-randomized group.
- ... and 2 more (see full listing online)

## Locations (3 total)

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Mayo Clinic, Phoenix, Arizona, United States  
Mayo Clinic, Jacksonville, Florida, United States  
Mayo Clinic, Rochester, Minnesota, United States

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<https://clinicaltrials.gov/study/NCT06568549>

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