UNIVERZITNÁ NEMOCNICA MARTIN
KOLLÁROVA 2, 036 59 MARTIN
TRANSPLANTAČNO-NEFROLOGICKÉ ODDELENIE
TRANSPLANT-NEPHROLOGY DEPARTMENT

STUDY TITLE

A Randomized Controlled Study of Daratumumab for Microvascular Inflammation (MVI) in Kidney Transplant Recipients With or Without Donor-Specific Antibodies

(DARA-MVI)

NCT number:

Transplantačno – Nefrologické oddelenie Univerzitná nemocnica Martin

tc@unm.sk
+ 421 43 4203 184

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In Martin, Slovakia 05th NOV 2025

Acronym

DARA-MVI Study (Daratumumab for Microvascular Inflammation in Kidney Transplantation)

Official Title

A Randomized Controlled Study of Daratumumab for Microvascular Inflammation (MVI) in Kidney Transplant Recipients With or Without Donor-Specific Antibodies

Brief Summary

The DARA-MVI Study is a prospective, randomized, controlled, open-label trial designed to evaluate the effect of daratumumab on microvascular inflammation (MVI) in kidney transplant recipients with C4d-negative biopsies. Participants with biopsy-proven MVI will be randomized to receive either daratumumab or observation with standard monitoring. The study will assess changes in histologic MVI score, donor-derived cell-free DNA (dd-cfDNA), donor-specific antibodies (DSA), and graft function over 12 months.

Study Design

Type: Interventional (Clinical Trial)

Allocation: Randomized (1:1 ratio)

Intervention Model: Parallel Assignment

Masking: Open-label (pathology and laboratory assessments blinded)

Primary Purpose: Treatment

Estimated Enrollment: 80 participants (40 per cohort)

Randomization: Block randomization (block size = 4) using MedCalc software Duration: 12-month follow-up per participant

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Arms and Interventions

Arm A – Observation: Participants with MVI, C4d-negative, and DSA-negative will undergo observation with standard monitoring. DSA and dd-cfDNA will be measured every 3 months for 12 months.

Arm B – Daratumumab: Daratumumab 1800 mg subcutaneously once monthly × 3 doses plus standard monitoring of DSA and dd-cfDNA every 3 months.

Control Group: Biopsy-negative, DSA-negative, dd-cfDNA-negative patients matched for time post-transplant and donor type.

Outcome Measures

Primary Outcome: Change in microvascular inflammation score (Banff g + ptc) between baseline and 12 months.

Secondary Outcomes:

1. Change in eGFR from baseline to 12 months.

2. Development of de novo DSA.

3. Change in dd-cfDNA (% and copies/mL).

4. Histologic resolution/progression of MVI.

5. Adverse events related to daratumumab.

6. Patient and graft survival at 12 months.

Eligibility Criteria

Inclusion: Age ≥ 18, kidney transplant recipients (first or higher, living or deceased donor), biopsy-proven MVI (g ≥ 1 and/or ptc ≥ 1), C4d-negative, DSA-negative (Cohort 1) or DSA-positive (Cohort 2), informed consent.

Exclusion: C4d-positive biopsy, active TCMR ≥ IA, infection or malignancy, multi-organ transplant, prior anti-CD38 therapy, pregnancy, breastfeeding.

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Timeline

Start: March 2026 | Primary completion: March 2027 | Study completion: September 2027

Locations

University Hospital Martin, Slovakia

Principal Investigator

Ivana Dedinská, MD, PhD – Transplant Nephrology Unit

Keywords

Kidney transplantation, MVI, daratumumab, dd-cfDNA, DSA, plasma cell therapy, C4d-negative rejection

tc@unm.sk
+ 421 43 4203 184