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TRANSPLANTAČNO-NEFROLOGICKÉ ODDELENIE
TRANSPLANT-NEPHROLOGY DEPARTMENT

STUDY TITLE

Predicting Outcomes in Diabetes via microRNA

PRODIGY

NCT number:

In Martin, Slovakia 27th May 2025

Transplantačno – Nefrologické oddelenie
Univerzitná nemocnica Martin

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1. Research Question and Objectives:

- **Primary Research Question:** Can specific microRNA profiles at 3 months post-kidney transplant predict the development of PTDM?
- **Secondary Research Question:** How do traditional risk factors (age, immunosuppression, obesity, CMV infection) and their interaction with specific
- **Primary Objective:** To identify a panel of microRNAs at 3 months post-kidney transplant that are significantly associated with the development of PTDM within a defined follow-up period (e.g., 1 year, 2 years).
- **Secondary Objectives:**
  - To assess the association between traditional risk factors (age, immunosuppression, obesity, CMV infection) and the development of PTDM.
  - To investigate the interaction between specific microRNAs and traditional risk factors in predicting PTDM.
  - To explore the correlation between specific microRNA expression

2. Study Design:

- **Type:** Prospective Observational Cohort single center Study

3. Study Population:

- **Inclusion Criteria:**
  - Adult patients undergoing kidney transplantation.
  - Absence of pre-existing type 1 or type 2 diabetes mellitus.
  - Willingness to provide informed consent and comply with study procedures.
- **Exclusion Criteria:**
  - Pre-existing type 1 or type 2 diabetes mellitus.
  - Previous organ transplantation.
  - Severe comorbidities that could confound the assessment of PTDM (e.g., pancreatic disease).
  - Inability to provide informed consent.
- **Recruitment:**
  - Consecutive enrollment of eligible patients undergoing kidney transplantation at your center(s).
- **Total Sample Size:** 64 patients (PTDM group) + 64 patients (non-PTDM group) = 128 patients

4. Data Collection and Procedures – see table 1:

- **Baseline Data:**
  - Demographics (age, sex, ethnicity)
  - Medical history (including pre-transplant comorbidities)
  - Transplant-related data (donor source, cold ischemia time, etc.)
  - Immunosuppression regimen (specific drugs and dosages)
  - Weight, height (for BMI calculation)
  - CMV status (pre- and post-transplant)
- **3-Month Visit:**

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- Blood sample for microRNA profiling (collect and store appropriately for later analysis)
- Oral Glucose Tolerance Test (oGTT) - Follow standardized protocols for administration and interpretation.

- **12-month Follow-up:**
  - Regular monitoring for the development of PTDM (based on established diagnostic criteria, e.g., ADA criteria).
  - Collection of data on immunosuppression changes, CMV infections, and other relevant clinical events.
  - Define a specific follow-up period (e.g., 1 year, 2 years) to determine the incidence of PTDM.

5. Outcome Measures:

- **Primary Outcome:** Development of PTDM within the defined follow-up period (diagnosed according to ADA criteria or other established criteria).
- **Secondary Outcomes:**
  - Specific microRNA expression levels at 3 months.
  - Correlation between microRNA expression and oGTT results.
  - Association between traditional risk factors and PTDM.
  - Interaction between microRNAs and traditional risk factors in predicting PTDM.

6. Data Analysis:

- **Statistical Methods:**
  - Repeated Measures Analysis: statistical methods that can handle repeated measures data, such as repeated measures ANOVA or mixed-effects models.
  - Correlation Analysis: correlation between microRNA expression levels and the results of the standard oGTT

	base line	M3	M12
Age at KT (years)	X		
Donor type (SCD/ECD/living)	X		
Weight (kg)	X	X	X
Waist circumference (cm)	X	X	X
BMI (kg/m²)	X	X	X
ADPKD (yes/no)	X		
Duration of dialysis (months)	X		
Family history of DM*	X		
Induction (basiliximab/ATG)	X		
TAC level (ng/ml)		X	X
Corticosteroid dose (mg/day)		X	X
History of acute rejection		X	X
- If yes, treatment (CS/IA/PF/IVIg/Rtx/dara)		X	X
OGTT – standard**	X	X	X
HbA1c (%)		X	X
C-peptide (µg/l) fasting + 2 hours after meal		X	X
Immunoreactive insulin (mU/l) + 2 hours after meal		X	X
HOMA-IR		X	X
eGFR (ml/min)		X	X
Creatinine (µmol/l)		X	X
cholesterol (mmol/l)		X	X
LDL (mmol/l)		X	X

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HDL (mmol/l)		X	X
Triglycerides (mmol/l)		X	X
Hb (g/l)		X	X
CMV PCR (cop/ml)		X	X
microRNA		X	

M – month, KT – kidney transplantation, SCD – donor with standard criteria, ECD – donor with expanded criteria, BMI – body mass index, ADPKD – autosomal dominant polycystic kidney disease, DM – diabetes mellitus, ATG – antithymocyte globulin, TAC – tacrolimus, KS – corticosteroids, IA – immunoadsorption, PF – plasma exchange, IvIg – intravenous immunoglobulins, RTx – rituximab dara – daratumumab, oGTT – oral glucose tolerance test, HbA1c – glycated hemoglobin, eGFR – estimated glomerular filtration rate (according to CKD-EPI), LDL – low-density lipoproteins, HDL – high-density lipoproteins, Hb – hemoglobin, CMV – cytomegalovirus, PCR – polymerase chain reaction

*Parents, grandparents, siblings, children

** OGTT will be performed in patients without antidiabetic treatment (insulin and/or oral antidiabetics)

Table 1

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