

# RESEARCH YOUR CHOICE

*SMH Kidney Research Team*



**DR. YUEN**



**IN THE LAB**

**IN THE CLINIC**



# In the Lab

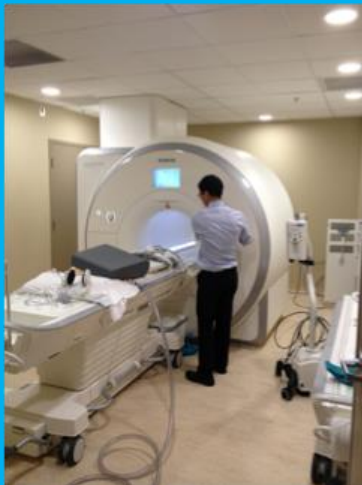
- Understanding how your transplant kidney becomes damaged
- Using that knowledge to develop new:
  - diagnostic tests
  - treatments



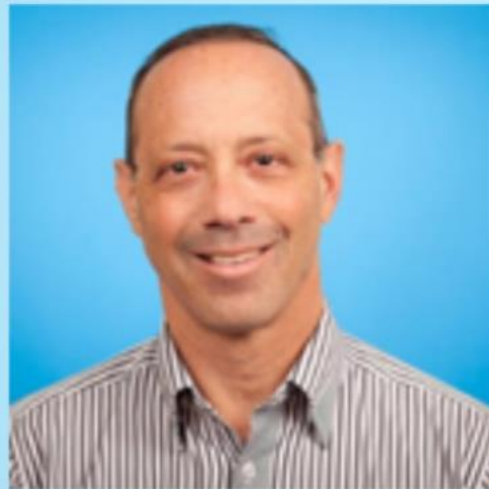
# In the Clinic



- First-in-human testing of these new:
  - Diagnostic procedures
  - Treatments
- Improve the care of patients with kidney transplants and chronic kidney disease



# DR. ZALTZMAN



RESEARCH  
FAVORITES

HOT TOPICS



# Research Favourites

- Studying the effects of once daily tacrolimus, on kidney blood flow and kidney filtration
- Testing new drugs for transplant: cyclosporine, sirolimus, everolimus, once-daily tacrolimus, belatacept
- Testing antibiotics ( Azithromycin) in reducing gum growth related to cyclosporine



# Research Favourites

- Helping to test a new safe vaccine for shingles in renal transplant patients
- Looking at kidney transplant outcomes in patients who partook in “transplant tourism”
- Developing and reporting on our national “kidney paired donation system”
- Studying transplant results in donation after cardiac death organ donors



# Hot Topics

- How to keep kidneys lasting longer, preventing and treating antibody mediated rejection
- How to manage patients on the wait-list, ( cardiac testing)
- Preventing/ reducing effects of delayed graft function





# Clinical Trials

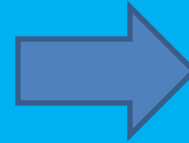
Michelle Nash  
Research Manager

Where to  
find more  
info?



# How to find out more?

- [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)



ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 270,894 research studies in all 50 states and in 203 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

**IMPORTANT:** Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

### Find a study (all fields optional)

#### Recruitment status ⓘ

- Recruiting and not yet recruiting studies
- All studies

#### Condition or disease ⓘ (For example: breast cancer)

#### Other terms ⓘ (For example: NCT number, drug name, investigator name)

#### Country ⓘ

 X

Search

[Advanced Search](#)

## Find a study (all fields optional)

### Recruitment status

- Recruiting and not yet recruiting studies
- All studies

### Condition or disease (For example: breast cancer)

kidney transplant

### Other terms (For example: NCT number, drug name, investigator name)

### Country

Canada



X

### City

Toronto

### Distance



Search

[Advanced Search](#)

Hide Filters

Filters

Apply Clear

Recruitment Status

Clinical Study

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn
- Unknown status\*

Expanded Access

Eligibility Criteria

Age

years OR

Age Group

- Child (birth-17)
- Adult (18-65)
- Senior (66+)

Sex

- All
- Female
- Male

Accepts Healthy Volunteers

Study Type

Study Results

Study Phase

Funder Type

Apply Clear

Showing: 1-10 of 35 studies 10 studies per page

| Row | Saved                    | Status                  | Study Title                                                                                                                              | Conditions                                                                                                                                                                                                          | Interventions                                                                                                                | Locations                                                                                                                                                                                                                                                                                                         |
|-----|--------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | <input type="checkbox"/> | Terminated              | <a href="#">Mycophenolate Mofetil for Reducing Cardiovascular Risk in Renal Transplant Recipients</a>                                    | <ul style="list-style-type: none"> <li>• Kidney Transplantation</li> <li>• Cardiovascular Diseases</li> </ul>                                                                                                       | <ul style="list-style-type: none"> <li>• Drug: mycophenolate mofetil</li> <li>• Other: standard immunosuppression</li> </ul> | <ul style="list-style-type: none"> <li>• St. Michael's Hospital<br/>Toronto, Ontario, Canada</li> </ul>                                                                                                                                                                                                           |
| 2   | <input type="checkbox"/> | Enrolling by invitation | <a href="#">The Feasibility and Safety of Normothermic ex Vivo Kidney Perfusion</a>                                                      | <ul style="list-style-type: none"> <li>• Kidney Transplantation</li> </ul>                                                                                                                                          | <ul style="list-style-type: none"> <li>• Drug: Normothermic ex-vivo kidney perfusion Solution -Toronto</li> </ul>            | <ul style="list-style-type: none"> <li>• University Health Network<br/>Toronto, Ontario, Canada</li> </ul>                                                                                                                                                                                                        |
| 3   | <input type="checkbox"/> | Completed               | <a href="#">Intraoperative Fluid Therapy for Deceased Donor Renal Transplantation</a>                                                    | <ul style="list-style-type: none"> <li>• Kidney Failure</li> </ul>                                                                                                                                                  | <ul style="list-style-type: none"> <li>• Device: Esophageal Doppler Monitor</li> </ul>                                       | <ul style="list-style-type: none"> <li>• Toronto General Hospital<br/>Toronto, Ontario, Canada</li> </ul>                                                                                                                                                                                                         |
| 4   | <input type="checkbox"/> | Completed               | <a href="#">Renal Function and Pharmacogenetics in Renal Transplant Recipients Converted From Tac BID to Tac OD</a>                      | <ul style="list-style-type: none"> <li>• Real Function Post Conversion From Prograf to Advagraf</li> <li>• Examin Ethnicity and Pharmacogenetics of the Cohort Requiring Dose Adjustment Post-conversion</li> </ul> |                                                                                                                              | <ul style="list-style-type: none"> <li>• St.Michael's Hospital<br/>Toronto, Ontario, Canada</li> </ul>                                                                                                                                                                                                            |
| 5   | <input type="checkbox"/> | Active, not recruiting  | <a href="#">Immunogenicity and Safety of Human Papilloma Virus Vaccine in Solid Organ Transplant Recipients</a>                          | <ul style="list-style-type: none"> <li>• Late Complication From Kidney Transplant</li> <li>• Complication of Transplanted Liver</li> <li>• Human Papillomavirus-Related Carcinoma</li> </ul>                        | <ul style="list-style-type: none"> <li>• Drug: Quadrivalent human papillomavirus vaccine</li> </ul>                          | <ul style="list-style-type: none"> <li>• The Hospital for Sick Children<br/>Toronto, Ontario, Canada</li> </ul>                                                                                                                                                                                                   |
| 6   | <input type="checkbox"/> | Completed               | <a href="#">Pharmacogenetic Trial of Tacrolimus After Pediatric Transplantation</a>                                                      | <ul style="list-style-type: none"> <li>• Heart Transplantation</li> <li>• Liver Transplantation</li> <li>• Kidney Transplantation</li> </ul>                                                                        | <ul style="list-style-type: none"> <li>• Drug: Tacrolimus</li> </ul>                                                         | <ul style="list-style-type: none"> <li>• The Hospital for Sick Children<br/>Toronto, Ontario, Canada</li> </ul>                                                                                                                                                                                                   |
| 7   | <input type="checkbox"/> | Active, not recruiting  | <a href="#">Implementing "Explore Transplant" - A Pilot Study</a>                                                                        | <ul style="list-style-type: none"> <li>• Endstage Kidney Disease</li> </ul>                                                                                                                                         | <ul style="list-style-type: none"> <li>• Other: Implementing "Explore Transplant" Education</li> </ul>                       | <ul style="list-style-type: none"> <li>• Humber River Hospital<br/>Toronto, Ontario, Canada</li> <li>• Toronto General Hospital<br/>Toronto, Ontario, Canada</li> </ul>                                                                                                                                           |
| 8   | <input type="checkbox"/> | Completed               | <a href="#">Quinolone Prophylaxis for the Prevention of BK Virus Infection in Kidney Transplantation: A Pilot Study</a>                  | <ul style="list-style-type: none"> <li>• Disease Due to BK Polyomavirus</li> <li>• Kidney Transplant Infection</li> </ul>                                                                                           | <ul style="list-style-type: none"> <li>• Drug: Levofloxacin</li> </ul>                                                       | <ul style="list-style-type: none"> <li>• Capital Health - University of Alberta Hospital<br/>Edmonton, Alberta, Canada</li> <li>• Vancouver General Hospital<br/>Vancouver, British Columbia, Canada</li> <li>• St. Paul's Hospital<br/>Vancouver, British Columbia, Canada</li> <li>• (and 8 more...)</li> </ul> |
| 9   | <input type="checkbox"/> | Completed               | <a href="#">Study of Immunosuppressive Therapy Toxicities in Kidney Transplant Recipients at Regional or Satellite Community Clinics</a> | <ul style="list-style-type: none"> <li>• Kidney Transplantation</li> </ul>                                                                                                                                          | <ul style="list-style-type: none"> <li>• Other: Chart Review</li> </ul>                                                      | <ul style="list-style-type: none"> <li>• New Westminster, British Columbia, Canada</li> <li>• Vancouver, British Columbia, Canada</li> <li>• Moncton, New Brunswick, Canada</li> <li>• (and 10 more...)</li> </ul>                                                                                                |
| 10  | <input type="checkbox"/> | Unknown*                | <a href="#">Coronary Artery Disease Screening in Kidney Transplant Candidates</a>                                                        | <ul style="list-style-type: none"> <li>• End Stage Renal Disease</li> <li>• Coronary Artery Disease</li> </ul>                                                                                                      | <ul style="list-style-type: none"> <li>• Other: Selective Screening</li> </ul>                                               | <ul style="list-style-type: none"> <li>• St. Paul's Hospital<br/>Vancouver, British Columbia, Canada</li> <li>• Vancouver General Hospital<br/>Vancouver, British Columbia, Canada</li> <li>• The Ottawa Hospital<br/>Ottawa, Ontario, Canada</li> <li>• (and 2 more...)</li> </ul>                               |





# LAB BASED STUDIES

Weiqiu Yuan  
Research Assistant



ANEMIAT



AMINODAT



# ANEMIAT

- **What is it?**

- An observational study

- Purpose:

to compare kidney transplant patients with anemia and without anemia to see if hemoglobin concentrations after a kidney transplant are related to different biomarkers( such as GDF-15, GDF-11, hepcidin and serum erythropoietin)

- **Who is involved?**

- 90 participants at SMH

- **How is it set up?**

| Study groups       |                    | Target |
|--------------------|--------------------|--------|
| Anemia<br>(45)     | Diabetes (type II) | 15     |
|                    | Non-diabetes       | 30     |
| Non-Anemia<br>(45) | Diabetes (type II) | 15     |
|                    | Non-diabetes       | 30     |

# ANEMIAIAT

- **What is involved?**

- Only 1 visit required
- Non-fasting blood samples
- Medical history and medication review
- Measurements: weight, height, waist and hip circumference, sitting blood pressure and heart rate

- **What have been done?**

- Enrollment to date: 23

| Study groups       |                    | Target | Enrollment |
|--------------------|--------------------|--------|------------|
| Anemia<br>(45)     | Diabetes (type II) | 15     | 2          |
|                    | Non-diabetes       | 30     | 3          |
| Non-Anemia<br>(45) | Diabetes (type II) | 15     | 4          |
|                    | Non-diabetes       | 30     | 14         |





# AMINODAT

- **What is it?**

- An observational study

- Purpose:

to determine the association between selected fasting amino acid profiles and the presence of glucose (sugar) metabolism abnormalities in end stage renal disease and kidney transplant populations.

- **Who is involved?**

- 90 participants at SMH

- **How is it set up?**

| Study groups            |                    | Target |
|-------------------------|--------------------|--------|
| Pre-transplant<br>(45)  | Diabetes (type II) | 15     |
|                         | Non-diabetes       | 30     |
| Post-transplant<br>(45) | NODAT              | 15     |
|                         | Non-NODAT          | 30     |

# AMINODAT

- **What is involved?**

- Only 1 visit required
- Participant with diabetes: *fasting blood samples*  
Participant with non-diabetes: *fasting blood samples plus 2 hrs OGTT*
- Medical history and medication review
- Measurements: weight, height, waist and hip circumference, sitting blood pressure and heart rate

- **What have been done?**

| Study groups            |                    | Target | Enrollment |
|-------------------------|--------------------|--------|------------|
| Pre-transplant<br>(45)  | Diabetes (type II) | 15     | 15         |
|                         | Non-diabetes       | 30     | 21         |
| Post-transplant<br>(45) | NODAT              | 15     | 15         |
|                         | Non-NODAT          | 30     | 30         |



# CLINICAL RESEARCH


Lindita Rapi  
Research Coordinator

RISKS AND  
BENEFITS

RESEARCH  
CURIOSITY

RIGHTS AND  
PROTECTIONS





# **Risks/disadvantages** of participating in a clinical trial

Lindita Rapi  
Research Coordinator



# Interventional Studies

- There are risks involved
- However, by the time researchers are allowed to test a new medication on volunteers there is a reasoning and some evidence on safety
- The more a medication has been tested, more we know about it

# Interventional Studies

- The health of research participants is monitored very closely
- All research is reviewed by a Research Ethics Board ( Respect for Persons, Concern for Welfare, Justice)
- Bottom line: Participants' safety comes first

# Observational Studies

- Observational Studies (data collection) or Lab Studies ( blood samples) have minimal risks

# Best advice

- Speak directly with the Research Team and your Study Doctor, do not hesitate to ask questions







# Benefits/ advantages of participating in a clinical trial

Lindita Rapi  
Research Coordinator



# Benefits/ advantages of participating in a clinical trial

- Often no direct benefit
- However, participants may have access to potential treatments-otherwise not available
- The treatment could prove to be a success

# Benefits/ advantages of participating in a clinical trial

- May enjoy the extra attention from a dedicated research team
- May like having more follow up tests/ procedures
- Help future generations and others with the same disease



Clinical Trial Participants **Rights**  
**and Protection**

Lindita Rapi  
Research Coordinator





# The Rights

- The right to refuse to participate
- Ask for information and fully understand what is to be expected
- The right to ask for more time if needed

# The Rights

- Expect protection of your personal health information to the extent permitted by law
- Know any side effects that might be known in advance
- The right to leave the study at any time





# Clinical Research Curiosity

Lindita Rapi  
Research Coordinator



# Facts about Clinical Research

1. It takes approximately 10 years for a drug to reach from the lab to clinical trials

2. Molecule → Labs → Clinical Trials → Market  
10,000 → 250 → 10 → 1

(source: Economist)



# Facts About Clinical Research

## How do people hear about clinical research?

1. 14% of people through their physician
2. 48% through media and advertisement
3. 75% of people say their physician is their most trusted source.

# Facts about Clinical Research

- 70% of people do not know what questions to ask when consenting

# What do people consider when deciding to participate in a clinical trial

- “If it would benefit me or someone else” (58%)
- “If I knew all about the risks” (48%)
- “If the risk was minimal or if the reward outweighs the risk” (35.3%)
- “For a cure” (35.2%)
- “If my doctor recommended it” (34.5%)

( source: Harris Interactive)

# Key players in a Clinical Trial

- The Sponsor,
- The Study Doctor,
- The Research Team,
- Medical staff,
- Participants

*“Patients and caregivers are the heart and soul of research”*

*A researcher*

# The Kidney Research Team

- Dr. Jeffrey Zaltzman
- Dr. Ramesh Prasad
- Dr. Darren Yuen
- Dr. Phil McFarlane
- Niki Dacouris
- Lindita Rapi
- Weiqiu Yuan
- Michelle Nash
- Galo Ginocchio
- Michael Huang

... plus many students, residents, fellows, volunteers!