TransplantLines Food and Nutrition Biobank and Cohort Study (TxL-FN)

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22374

Source
NTR

Brief title
TxL-FN

Health condition

Short-term (1-year) results of renal transplantation are now excellent (over 95%). Long-term (10-year and longer) results are, however, still disappointing. Where most research has focused on immunosuppression and infections, we hypothesize that due to poor homeostatic capacity and necessary use of immunosuppressive and other drugs, renal transplant recipients are much more susceptible to poor dietary habits and exposure to potentially toxic contaminants than people of the general population, and that this contributes to accelerated function loss of the graft and excess risk of premature mortality, both contributing to poor long-term results.

To investigate one part of this overarching hypothesis we wrote a project on around the specific topic of the relation between dietary acid load, ammoniagenesis and its potential influence on blood pressure. We used this project to build a biobank and cohort in which we can test additional hypotheses on the relation between diet, contaminants and development of graft failure and the occurrence of mortality.

We also included 300 healthy controls to compare diet, contaminant exposure and biomarkers with the renal transplant recipients.

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Top Institute Food and Nutrition (grant A-1003)

Intervention

Outcome measures

Primary outcome

Graft failure and all-cause mortality

Secondary outcome

Cause-specific graft failure
Cause-specific mortality
Change in renal function
Development of new-onset diabetes after transplantation

Study description

Background summary

The baseline measurements of the cohort have been performed between 21-11-2008 and 24-05-2011. In this time, 707 renal transplant recipients and 300 healthy potential living kidney donors have been included. The baseline measurements were complemented with a biobank of serum, plasma and 24h urine samples stored at -80 degrees Centigrade. Included participants are now prospectively followed for development of outcome events.

Study objective

Short-term (1-year) results of renal transplantation are now excellent (over 95%). Long-term (10-year and longer) results are, however, still disappointing. Where most research has focused on immunosuppression and infections, we hypothesize that due to poor homeostatic capacity and necessary use of immunosuppressive and other drugs, renal transplant recipients are much more susceptible to poor dietary habits and exposure to potentially toxic contaminants than people of the general population, and that this contributes to accelerated function loss of the graft and excess risk of premature mortality, both contributing to poor long-term results. This study is a biobank and cohort study which investigates this hypothesis.

Study design

Baseline measurements
Routine outpatient clinical visits

Intervention

No interventions, the cohort is observational

Contacts

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Eligibility criteria

Inclusion criteria

More than one year after transplantation, prognosis > 1 year, stable outpatients situation

Exclusion criteria

Acute illnesses, fever, current hospitalisation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	21-11-2008
Enrollment:	1000
Type:	Unknown

Ethics review

Positive opinion

Date:	21-06-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5673
NTR-old	NTR5910
Other	TransplantLines Food and Nutrition : METc2008/186

Study results

Summary results

1: Frenay AR, Kayacelebi AA, Beckmann B, Soedamah-Muhtu SS, de Borst MH, van den Berg E, van Goor H, Bakker SJ, Tsikas D. High urinary homoarginine excretion is associated with low rates of all-cause mortality and graft failure in renal transplant recipients. Amino Acids. 2015 Sep;47(9):1827-36. doi: 10.1007/s00726-015-2038-6. Epub 2015 Jul 5. PubMed PMID: 26142633.

2: Frenay AR, van den Berg E, de Borst MH, Beckmann B, Tsikas D, Feelisch M, Navis G, Bakker SJ, van Goor H. Plasma ADMA associates with all-cause mortality in renal transplant recipients. Amino Acids. 2015 Sep;47(9):1941-9. doi: 10.1007/s00726-015-2023-0. Epub 2015 Jun 16. PubMed PMID: 26077715; PubMed Central PMCID: PMC4549386.

3: Keyzer CA, de Borst MH, van den Berg E, Jahnen-Dechent W, Arampatzis S, Farese S, Bergmann IP, Floege J, Navis G, Bakker SJ, van Goor H, Eisenberger U, Pasch A. Calcification Propensity and Survival among Renal Transplant Recipients. J Am Soc Nephrol. 2016 Jan;27(1):239-48. doi: 10.1681/ASN.2014070670. Epub 2015 Apr 29. PubMed PMID: 25925688; PubMed Central PMCID: PMC4696561.

4: Baia LC, Van den Berg E, Vervloet MG, Heilberg IP, Navis G, Bakker SJ, Geleijnse JM, Kromhout D, Soedamah-Muthu SS, De Borst MH; NIGRAM consortium. Fish and omega-3 fatty acid intake in relation to circulating fibroblast growth factor 23 levels in renal transplant recipients. Nutr Metab Cardiovasc Dis. 2014 Dec;24(12):1310-6. doi: 10.1016/j.numecd.2014.06.006. Epub 2014 Jun 23. PubMed PMID: 25063539.

5: Zittema D, van den Berg E, Meijer E, Boertien WE, Muller Kobold AC, Franssen CF, de Jong PE, Bakker SJ, Navis G, Gansevoort RT. Kidney function and plasma copeptin levels in healthy kidney donors and autosomal dominant polycystic kidney disease patients. Clin J Am Soc Nephrol. 2014 Sep 5;9(9):1553-62. doi: 10.2215/CJN.08690813. Epub 2014 Jul 3. PubMed PMID: 24993447; PubMed Central

PMCID: PMC4152815.

6: van den Berg E, Pasch A, Westendorp WH, Navis G, Brink EJ, Gans RO, van Goor H, Bakker SJ. Urinary sulfur metabolites associate with a favorable cardiovascular risk profile and survival benefit in renal transplant recipients. J Am Soc Nephrol. 2014 Jun;25(6):1303-12. doi: 10.1681/ASN.2013050497. Epub 2014 Feb 7. PubMed PMID: 24511127; PubMed Central PMCID: PMC4033367.

7: Snijder PM, van den Berg E, Whiteman M, Bakker SJ, Leuvenink HG, van Goor H. Emerging role of gasotransmitters in renal transplantation. Am J Transplant. 2013 Dec;13(12):3067-75. doi: 10.1111/ajt.12483. Epub 2013 Oct 30. Review. PubMed PMID: 24266966.

8: Boxma PY, van den Berg E, Geleijnse JM, Laverman GD, Schurgers LJ, Vermeer C, Kema IP, Muskiet FA, Navis G, Bakker SJ, de Borst MH. Vitamin k intake and plasma desphospho-uncarboxylated matrix Gla-protein levels in kidney transplant recipients. PLoS One. 2012;7(10):e47991. doi: 10.1371/journal.pone.0047991. Epub 2012 Oct 31. PubMed PMID: 23118917; PubMed Central PMCID: PMC3485347.

9: van den Berg E, Engberink MF, Brink EJ, van Baak MA, Joosten MM, Gans RO, Navis G, Bakker SJ. Dietary acid load and metabolic acidosis in renal transplant recipients. Clin J Am Soc Nephrol. 2012 Nov;7(11):1811-8. doi: 10.2215/CJN.04590512. Epub 2012 Aug 30. PubMed PMID: 22935845; PubMed Central PMCID: PMC3488949.

10: van den Berg E, Engberink MF, Brink EJ, van Baak MA, Gans RO, Navis G, Bakker SJ. Dietary protein, blood pressure and renal function in renal transplant recipients. Br J Nutr. 2013 Apr 28;109(8):1463-70. doi: 10.1017/S0007114512003455. Epub 2012 Aug 21. PubMed PMID: 22906209.

11: van den Berg E, Geleijnse JM, Brink EJ, van Baak MA, Homan van der Heide JJ, Gans RO, Navis G, Bakker SJ. Sodium intake and blood pressure in renal transplant recipients. Nephrol Dial Transplant. 2012 Aug;27(8):3352-9. doi: 10.1093/ndt/gfs069. Epub 2012 Apr 12. PubMed PMID: 22499024.