Long-term follow-up of the offspring born to mothers with a solid organ transplant.

Published: 15-12-2024
Last updated: 25-03-2025

The primary aim of the study is to assess the overall health of offspring born to a mother with solid organ transplantation, and to identify possible pre- and perinatal risks for diseases later in life. In addition, we would like to collect and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON57189

Source
ToetsingOnline

Brief title
Transplantlines Next Generation

Condition

- Immune disorders NEC
- Genitourinary tract disorders NEC
- Vascular disorders NEC

Synonym
cardiovascular disease, nephrological disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Groninger Transplantatiefonds;Nederlandse TransplantatieVereniging,Astellas Pharma,grant voor

opbouwen database van Astellas;farmaceutisch bedrijf)

Intervention

Keyword: follow-up, offspring, pregnancy, solid organ transplantation

Outcome measures

Primary outcome

The primary endpoints of the study focus on cardiovascular health and the presence of kidney disease in participants >16 years, and overall health in participants =<16 years.This will be assessed by growth charts and developmental information retrospectively collected from the children*s health care center, physical tests (weight and height, body fat and water percentage (BIA), waist-hip-ratio, blood pressure, heart rate) and with biological samples (metabolic parameters: glucose, HbA1c, cholesterol, HDL, LDL, triglycerides, as well as kidney functional parameters: albuminuria, estimated GFR, tubular function).

Secondary outcome

Secondary aims are the immunological status, including microbiome and the overall development of the offspring. Third, we want to assess if there are differences between the health of the offspring born to mothers with a KTx, LiTx, HTx and LuTx.

Study description

Background summary

Studies have reported successful pregnancy outcomes with healthy newborns after all types of solid organ transplantations (SOT). A recent systematic review

performed by our center focused on the longer term outcomes (>1 year) of the children born after SOT. We found that data regarding longer term follow-up is scarce, limited to younger children and predominately focused on offspring born after kidney transplantation (KTx) and liver transplantation (LiTx). Only five studies reported outcomes on offspring aged >18 years. The limited existing data in young children are reassuring, development and overall health appears to be similar to the general population. However, it is possible that the development of the fetus is affected by the transplantation and its consequences such as the use of the immunosuppressive medication and the increased incidence of the pregnancy complications, whereby important health risks only become apparent later in life. To gain more insight into the overall health of the offspring born solid organ transplantation and to identify possible pre- and perinatal risks for diseases later in life we want to perform a cross-sectional cohort study. To the best of our knowledge, this will be the first study that will gather and analyze detailed information about the cardiovascular, immunological and kidney health at a later age (>=16 years) in the offspring born to mothers after KTx and LiTx, and the overall health of offspring born to mothers with a heart and lung transplantation (HTx, LuTx resp.)

Study objective

The primary aim of the study is to assess the overall health of offspring born to a mother with solid organ transplantation, and to identify possible pre- and perinatal risks for diseases later in life. In addition, we would like to collect and analyze detailed information on cardiovascular, immunological and renal health later in life (>=16 years) in offspring of mothers after KTx and LiTx, and would like to map the overall health of children of a mother with heart and lung transplantation (HTx, LuTx respectively).

Study design

This will be a descriptive cross-sectional monocenter cohort study. All offspring >=16 years of age born after KTx or LiTx and all offspring born at any age after HTx and LuTx in the Netherlands will be eligible for inclusion. Eligible participants will be identified via previous studies on pregnancy after KTx, LiTx, HTx and LuTx. Participants will be invited for a one-time study visit consisting of questionnaires, physical tests (including blood pressure measurement and ultrasound of the kidneys) and biological sample (urine, blood and feces) collection. Next to that a 24-hour ambulatory blood pressure measurement will be performed in the participants >=16 years. The biological sample collection will include sample collection for a biobank. The collection will be in line with the Transplantlines Biobank and an amendment to the Transplantlines Biobank will be submitted and specific informed consent for linking the data of Transplantlines and the current study will be obtained from all participants. For all participants it will be emphasized that the invasive

test (blood sample) is optional, participants can still participate in the study if they don*t want a blood sample taken. For the participants aged <16 years of age no blood, urine and feces sample will be taken, and no ultrasound of the kidney will be performed and a dinamap blood pressure measurement instead of a 24-hour measurement will be performed. Furthermore, data on the pregnancy will be used from three recent national studies, data from the PARTOUT network (national working group on pregnancy after renal transplantation), national data collected on pregnancy after LiTx (manuscript in preparation) and national data on pregnancy after HTx and LuTx (manuscript in preparation). Information about the growth and development of the offspring and, if present, diseases and medication use will be collected from the medical files of the general practitioner and pharmacy (LSP) and from data from the youth healthcare check-ups. Permission to collect this data will be separately mentioned on the IC. As a control group we will evaluate whether reference values and / or data from existing birth cohorts are available. If not, pseudo anonymized data from the Lifelines cohort will be used.

Study burden and risks

The burden for the participants consists of a one-time study visit to the hospital which will take approximately 1,5/2 hours and a 24-hour ambulatory blood pressure measurement after the study visit. The visit will consist of questionnaires and basis physical tests (e.g. weight, height, blood pressure) and an ultrasound of the kidneys. During this visit the following biological samples will be collected: one blood sample consisting of 38 tubes (1275 ml blood), a first morning urine sample and a feces sample. For the participants <16 years of age no blood, urine and feces sample will be taken. We consider this burden to be minimal. In the patient information we specifically mention that participants can still participate if they don*t want to participate in part of data collection (e.g. the blood sample or the ultrasound). If indications for disease or abnormal results are found during the study, the participant and the general practitioner of the participant will be contacted.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Mother with a Kidney Tx, Liver Tx, Heart Tx or Lung Tx before pregnancy (including mothers with multiple transplantation types)
• Age >=16 years for offspring born to mother with a KTx or LiTx

Exclusion criteria

• No informed consent
• Non Dutch or English speaking

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	210
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-12-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	27-02-2025
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL85646.042.23