Impact on Neurocognitive Performance in Children, Adolescents and Young Adults of Chronic Kidney Disease and its Therapy: A Feasibility Study.

Published: 02-06-2017
Last updated: 13-04-2024

The primary objective of the current study is to determine the relevance, feasibility and strain for patients of the INPACT protocol.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON47563

Source
ToetsingOnline

Brief title
The INPACT: a feasibility study

Condition

- Renal disorders (excl nephropathies)

Synonym
chronic kidney disease, familial uremia, kidney failure

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC locatie AMC
Source(s) of monetary or material Support: Nederlandse nierstichting en eigen

restantgeld uit eerder verkregen subsidies

Intervention

Keyword: adaptive functioning, brain networks, cognitive impairments, Renal transplantation

Outcome measures

Primary outcome

The main study outcome of the current study is relevance, feasibility and strain for patients of the INPACT protocol, as felt by the participants themselves (and as perceived by their parents too, for children < 18 years of age). Semi-structured interviews will be conducted by telephone to collect these data.

We will also systematically record: the number of approached patients who declined participation, reasons for non-participation, and % completion of the study protocol by participants (completion and response rates).

Based on these data, feasibility for enrolment of sufficiently large samples for the intervention study (the INPACT study) will be determined and the study protocol will adjusted if necessary.

Secondary outcome

Neurocognitive functioning will be assessed by neuropsychological test administration.

Medical parameters are derived from the medical records.

Brain structure and activity will be measured with MRI-scans (including DTI) and qEEG recording.

Adaptive functioning, behavior, health perception, quality of life, sleep and

sociodemographic background will be assessed by a variety of questionnaires.

Study description

Background summary

Cognitive impairment is a well-recognized disabling problem in children and adolescents with childhood onset chronic kidney disease (CKD). In CKD, decreased health related quality of life (HRQoL), delayed autonomy development and poorer adaptive functioning is also commonly found. Little is known on the mechanisms underlying cognitive impairment in CKD, nor on how cognition estimates the latter three concepts. More specifically, so far it is not clear what the effects of the disease (e.g. concentrations of uremic toxins) itself are, or how different strategies of renal replacement therapy (i.e. dialysis and renal transplantation) impact on cognition. We designed a longitudinal multicenter study in order to investigate substrates for cognitive dysfunctioning, to explore the effects of changes in renal replacement therapy on cognitive functioning and to analyze how cognitive dysfunctioning percolates adaptive functioning, behavior, health perception and HRQoL in childhood and young adult onset CKD, the so-called INPACT study.

Study objective

The primary objective of the current study is to determine the relevance, feasibility and strain for patients of the INPACT protocol.

Study design

The design of this feasibility study is a cross-sectional, observational study.

Study burden and risks

Participants spent approximately 6 hours in our hospital. During their visit they will undergo neuropsychological test administration, MRI-scanning (including DTI), and qEEG-registration. Beforehand, they fill out questionnaire online (www.hetklikt.nu) from home. Afterwards a semi-structured interview will be held by telephone. EEG and MRI measurements are non-invasive and participants will be thoroughly screened and prepared for the measurements. Children are able to practice the scanning in a mock scanner prior to the actual MRI scan. During the MRI scan, participants can wear earplugs, listen to music or they can play a movies of their own choice to make the scanning as comfortable as possible.
In all, risks of this non-therapeutic study are negligible and the burden is

object of study.

Contacts

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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)
Elderly (65 years and older)

Inclusion criteria

Inclusioncriteria for patients with CKD:
* Patients with CKD 4-5/ESRD or ESRD patients who underwent renal transplantation at least one years ago.
* aged 8-30 years.
* Sufficient visual and hearing acuity
* Dutch language fluency

* Willingness to give informed consent;Inclusioncriteria for three patients with familial uremia:
* Diagnosis of familial uremia.
* age 12 to 50 years
* Sufficient visual and hearing acuity
* Dutch language fluency
* Willingness to give informed consent;Healthy controls must meet all of the following criteria
* Sibling of the candidate, healthy classmate or close friend of the CKD patient.
* No diagnosis of CKD, or other chronic disease with primary or secondary CNS involvement
* Informed consent obtained from the participant or legal guardian if the participant is below 18 years
* age 8-30 year
* Sufficient visual and hearing acuity
* Dutch language fluency
* Willingness to give informed consent

Exclusion criteria

For both patients and healthy controls:
* Pre-existing documented cognitive impairment
* Active, uncontrolled psychiatric illness
* Substance abuse
* A history of cerebrovascular disease (either transitory ischaemic attack or cerebrovascular accident)
* Brain injury
* Epilepsy
* Diabetes mellitus
* Patients will be excluded from MRI scanning in case of MR contraindications, including implanted active devices or objects (e.g. cardiac pacemaker, implantable defibrillator, medication pump, intracranial aneurysm clips, cochlear implant and other implants), metal splinters near sensitive organs (e.g. eye, brain or lungs) or claustrophobia. They are eligible to participate in the other measurements of the study protocol.
* Any condition that can be expected to interfere with complete follow-up
* Patients participating in group 1 of the ALLEGRO trial (adult patients)
* HLA-identical family transplantations

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:	Recruitment stopped
Start date (anticipated):	16-06-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	02-06-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL61708.018.17