Renal Insufficiency Therapy in Children: Quality Assessment and Improvement.

Published: 12-07-2007
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To improve the quality of care for children with End Stage Renal Disease by central registration and frequent intervision.

Ethical review	-
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON31239

Source
ToetsingOnline

Brief title
RICH-Q

Condition

- Heart failures
- Nephropathies
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
chronic renal failure, renal replacement therapy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: 1.children, 2.chronic renal replacement therapy, 3.quality assessment and 4.improvement, cardiovascular comorbidity

Outcome measures

Primary outcome

In the research protocol a list is shown with all quality indicators that are

to be meausured. Most of them are normal contrals that are allready routinely

done, some are extra measurements that will be doen once a year. with these

quality indicators assessment of the quality of care of children with renal

Replacxement therapy will be done and by peer intervision we hope to improve

the therapy.

Secondary outcome

cardiovascular co-morbidity

mortality

Study description

Background summary

Despite all progress that has been made in the quality of renal replacement therapy (RRT) in children over the last 30 years, the overall mortality and morbidity at young adult age has remained unacceptable high. According Dutch data (the LERIC study), the overall mortality risk is 30 times increased. Over 40% of the adult survivors daily suffer from somatic co-morbidity. As compared to the general population, their educational level is significantly lower and the unemployment is about twice as high as.
No data exist on the exact influence on these outcomes of the several treatment modalities, such as peritoneal dialysis, conventional haemodialysis, extended forms of haemodialysis and transplantation.
In the Netherlands and in Belgium, chronic renal replacement therapy in children is provided by 4, respectively 5 rather small medical centres. Until now, no structural corporation exists between these centres and there is no

consensus on general guidelines with respect to dialysis treatment or treatment after transplantation. From oral communication, the impression is that the centres have a quite different therapeutic approach of children with end-stage renal disease (ESRD).
Cardiovascular disease is the main caused of death in patients with paediatric ESRD. In adults with ESRD, several non-invasive diagnostic tools have been developed to detect cardiovascular disease and to predict the risk for early cardiac death. Reliable data in children with respect to these methods are scarce. Early detection and therapeutic intervention of cardiovascular disease appears to be essential in children with ESRD in order to prevent sudden death in early adulthood.
Central quality assessment by registration of certain treatment characteristics that predict outcome, i.e. quality indicators, in combination with a quality research project has proven to be an important tool to improve the quality of treatment. Recent international studies have shown that chronic peritoneal dialysis treatment in children under continuous quality surveillances indeed improves in quality.

Study objective

To improve the quality of care for children with End Stage Renal Disease by central registration and frequent intervision.

Study design

This is an observational noninvasive study.
It's a multicenter study in which all hospitals in The Netherlands and Belgium that take care of children with End Stage Renal Disease are involved. There are 4 hospitals in the Netherlands and 5 hospitals in Belgium that provide this care and will be involved in the study.

Study burden and risks

Because this study is observational and non invasive there's no extra risk associated with participation. The burden is minimized because the patient does'nt have to come extra, doesn't need to undergo extra venapunctions or whatsoever. The only burden there is is the time needed to perform the pulse wave velocity and to fill out the Quality of Life Questionnaires. Because the main objective of the study is to improve the quality of care, we think this benefit is more important than the time needed for participation.

Contacts

Public

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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

1. All Dutch and Belgian prevalent patients on chronic dialysis aged < 19 years old at start of the study
2. All incident Dutch and Belgian patients with End Stage Renal Disease < 19 years (dialysis and transplantation)

Exclusion criteria

-

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2007
Enrollment:	120
Type:	Actual

Ethics review

Not approved

Date:	28-03-2013
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	NL16726.018.07