The Thrombin generation Test in Kidney disease Study

Published: 05-03-2014
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The overall aim of this study is to evaluate the use of the thrombin generation test in patients with CKD, including haemodialysis-dependent patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON40216

Source
ToetsingOnline

Brief title
3TKS

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Renal disorders (excl nephropathies)

Synonym
coagulation disorders, kidney failure

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: St Elisabeth ziekenhuis afdeling klinische chemie en interne geneeskunde;gedeelte van de testen en bloedafnamebuizen worden gratis verstrekt door Synapse BV,Synapse BV

Intervention

Keyword: chronic kidney disease, end stage renal disease (ESRD), low molecular weight heparin (LMWH), thrombin generation

Outcome measures

Primary outcome

The main study endpoint in the CKD group is correlating a decrease in kidney function and/or an increase in proteinuria with a change in outcome of the TGT. In a subgroup with severe chronic kidney failure an increase in thrombophilic state, expressed in the TGT, after the start of ESA by their treating physician will be the study endpoint.

The main study endpoints in the ESRD group are 1) proving a better correlation between TGT and clinical episodes of bleeding and clotting than the current gold standard, anti-factor Xa activity, in patients with CKD and 2) providing more insight in the kinetics of LMWH treatment in kidney failure compared to healthy controls.

Secondary outcome

nvt

Study description

Background summary

Patients with chronic kidney disease (CKD) including end stage renal disease (ESRD) and/or proteinuria are known to have an increased risk of venous thromboembolic events (VTE) and acute coronary syndrome (ACS). In severe kidney disease erythropoietin synthesis is decreased, making the use of erythropoietin stimulating agents (ESA) necessary. This is also associated with a higher rate of stroke and VTE. Conversely, patients with CKD often experience bleeding complications after invasive medical procedures. The underlying coagulation

disorders remain largely unclear. Patients undergoing haemodialysis receive a dose of low molecular weight heparin (LMWH) with every dialysis session to prevent coagulation in the extracorporeal circuit. The efficacy is monitored in anti-factor Xa activity, the current gold standard, but since it weakly correlates with clinical episodes of clotting and bleeding, this remains controversial. There is a need for a test to indicate patients with CKD at risk for VTE and monitoring LMWH therapy. The aim of this study is to investigate if the thrombin generation test (TGT) is an eligible candidate.

Study objective

The overall aim of this study is to evaluate the use of the thrombin generation test in patients with CKD, including haemodialysis-dependent patients.

Study design

The CKD Study is a single centre observational cross-sectional study, and for the patients receiving ESA treatment the study is short-term longitudinal. The ESRD Study is a single centre short-term longitudinal study.

Study burden and risks

In the CKD group an extra tube of blood will be drawn with an already scheduled venepuncture. For the ESRD patients the blood draws will be taken from the dialysis system except for one, which will require an extra venepuncture. The controls will receive a prophylactic dose of LMWH and several blood draws at set time points. The risk for all participants will be negligible.

Contacts

Public
Sint Elisabeth Ziekenhuis

Hilvarenbeekseweg 60
Tilburg 5022 GC
NL
Scientific
Sint Elisabeth Ziekenhuis

Hilvarenbeekseweg 60
Tilburg 5022 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for eligibility
All participants must be
• > 18 years of age
• Willing and able to sign informed consent;Inclusion criteria for CKD Study
A potential subject who meets all of the following criteria will be included for participation in the CKD Study:
• A stable decrease in GFR (for 3 months) with any amount of proteinuria
• A normal GFR (>60 ml/min) with proteinuria of >2 grams per 24 hours
• Not hemodialysis-dependent;Inclusion criteria for ESRD Study
A potential subject who meets all of the following criteria will be included for participation in the ESRD Study:
• Non-artificial shunt
• Stable thrice weekly hemodialysis for more than 3 months (adequate Kt/V)
• Use of standard dose LMWH, dalteparine <50 kg 2500 EH, >50 kg 5000 EH
• Any amount of proteinuria;Healthy controls
Participants eligible for the control group will have to meet the following criteria
• A GFR >60
• No proteinuria
• No liver disease
• No anemia or thrombocytopenia
• No use of hormonal contraceptives
• Not pregnant
• No recent trauma or surgery < 4 weeks
• No medical history of stomach or duodenal ulcers

Exclusion criteria

Exclusion criteria for CKD and ESRD Study
A potential subject who meets any of the following criteria will be excluded from participation in both studies:
• Patients who use anticoagulants (vitamin K antagonists or therapeutic dose of LMWH) < 4 weeks
• Patients with trombocytopenia (<100 x 109 / L)
• Patients who are pregnant or use hormonal anticonceptives
• Have a known coagulation disorder
• Have a active malignancy or have been treated for malignancy up to twelve months prior to inclusion date
• Blood transfusion < 1 week
• Trauma or surgical procedure < 4 weeks
• Liver cirrhosis or other liver disease
• Participation in another research study

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-08-2014
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	05-03-2014

Application type:	First submission
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	10-06-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL45975.008.14