THE TREMOR STUDY: TACROLIMUS EXTENDED RELEASE, MOVEMENT DISORDERS AND OTHER NEUROCOGNITIVE EFFECTS

Published: 09-06-2016
Last updated: 20-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON43508

Source
ToetsingOnline

Brief title
TREMOR study

Condition

- Nephropathies

Synonym
kidney transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Chiesi Farmaceutici,unrestricted grant Chiesi Farmaceutici

Intervention

Keyword: calcineurin inhibitors, kidney transplantation, neurocognitive performance, tremor

Outcome measures

Primary outcome

The primary outcome is tremor as measured by the ANT Modules Pursuit and

Tracking.

Secondary outcome

Secondary outcomes include (1) a selection of neuropsychological assessments

from the ANT test battery, (2) tremor as measured by TETRAS (TRG Essential

Tremor Rating Assessment Scale), (3) a quality of life assessment and (4)

patient drug preference at the end of study.

Study description

Background summary

Renal transplantation is the optimal form of renal replacement therapy. Compared to dialysis, it increases patient survival and quality of life. Moreover, renal transplantation decreases the economic burden of end-stage-renal replacement therapy to society. After renal transplantation maintenance immunosuppressive therapy is necessary to control graft rejection. These immunosuppressive regimens are frequently associated with side effects, which might detract from the potential gain of the renal transplant. Conversion to another regimen or formula of a specific drug can then be beneficial to reduce side effects.

Study objective

The main objective of this study is to investigate whether kidney transplant recipient suffering from a tacrolimus-induced tremor can benefit from switching from conventional tacrolimus to LCPT, a new extended release preparation of

tacrolimus (Envarsus®), or cyclosporine (Neoral®).

Study design

Investigator-driven, open-label, prospective, randomized controlled trial.

Intervention

At baseline, participants will undergo pharmacokinetic testing, a quality of life assessment and a computerized neuropsychological test battery (the Amsterdam Neuropsychological Tasks or ANT battery). The ANT battery consists of several computerized tests measuring the basal cognitive processes that regulate daily functioning, including two modules that are well-suited to quantify tremors. At one month, participants will be randomized to (1) continuing their current tacrolimus preparation, (2) switching to Envarsus®, or (3) switching to Neoral®. After one month, the tests will be repeated. Then, the participants in the control group will also be switched to Envarsus®. After one month, all tests will again be repeated.

Study burden and risks

Participants will be asked to undergo three test cycles. Each cycle is expected to last 8 hours, so that the total required time for completing the study will amount to 24 hours over a period of three months. In each cycle, participants will give at least four 5ml blood samples over a period of six hours for pharmacokinetic testing (more if drug levels are out of range), fill out two questionnaires and undergo a 45-minute neuropsychological assessment. Participating in this study can be beneficial because it may result in a diminished tremor and an improved neurocognitive function. In addition, participants will receive 50 euros per cycle plus compensation for travel expenses and the option of choosing the drug that suited them best at the end of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age between 18-70 years
Recipient of a kidney transplantation more than one year ago
On a triple-low-dose immunosuppressive regimen including tacrolimus
Suffering from a tremor
Stable renal function
Able to give informed consent

Exclusion criteria

Not being able to understand the instructions for the tests
Chronic diarrhea
Use of protease inhibitors, azoles or sedatives
Thyroid dysfunction
Active psychiatric or neurologic disease
Use of psychotropic drugs, antiepileptics or B2-agonists
Excessive use of caffeine (more than 5 I.E. per day)
Excessive use of alcohol (more than 2 I.E. per day)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-08-2016
Enrollment:	66
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Advagraf
Generic name:	tacrolimus
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Envarsus
Generic name:	tacrolimus
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Neoral
Generic name:	cyclosporine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Prograft
Generic name:	tacrolimus
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2017
Application type:	First submission
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
EudraCT	EUCTR2015-005462-31-NL
CCMO	NL55948.018.15