Conversion from cyclosporine to tacrolimus followed by randomized C0 or C4 Bayesian monitoring stable liver transplant patients.

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Renal function improves when converting stable livertransplant patients from cyclosporin to tacrolimus; it also improves with Bayesian C4 monitoring compared to C0 monitoring on tacrolimus.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22214

Bron
NTR

Verkorte titel
FK 04

Aandoening

kidney fuction in livertransplantation patients

Ondersteuning

Primaire sponsor: MD. PhD. B. van Hoek
Overige ondersteuning: Astellas Pharma B.V

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- creatinine clearance calculated by BSA- corrected Cockcroft and Gault and MDRD between:
- baseline (day 1) and week 12 (end of C0)
- week 12 (end of C0) and week 24 (end of study)
- baseline (day 1) and week 24 (end of study

Toelichting onderzoek

Achtergrond van het onderzoek

We convert stable patients after liver transplantation from cyclosporin to tacrolimus. Then patients on tacrolimus are randomized to monitoring by C0 or by Bayesian C4 blood levels. Primary outcome measure is renal function.

Doel van het onderzoek

Renal function improves when converting stable livertransplant patients from cyclosporin to tacrolimus; it also improves with Bayesian C4 monitoring compared to C0 monitoring on tacrolimus.

Onderzoeksopzet

- week 0

- week 1

- week 3

- week 8

- week 12

- week 16

- week 20

- week 24

Onderzoeksproduct en/of interventie

Immunologically stable liver transplant recipients will be converted from a cyclosporine based regimen to a standard C0 measured tacrolimus based regimen with a target level of 4-8 ng/mg.

Following a three month period in which the effect of the switch in immunosuppressive regimen will be observed and the dose can stabilize, patients will be randomized on a 50%/50% bases, one group continuing the standard C0 measurement tacrolimusregimen, the other will be dosed accoring to equipotent C4 AUC levels of 90-130 ng*h/ml.

Patients already on tacrolimus can enter the study as a separate stratum in week 12. During the following three months the effect of the C4 dosing will be compared tot the C0 dosing.

The total duration of the study is six months.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient age 18 years or older

2. Recieved a calcineurin-based immunosuppressive regimen since last transplantation

3. Patient is recipent of a liver transplant at least 6 months to entry into the study

4. Immunosuppressive regimen (combination of medications) remained unchanged for a minimum of 4 weeks prior to enrolment

5. Female patients of child bearing potential must have a negative urine of serum pregnacy test prior to enrolment and must agree to practice effctive birth control during the study

6. Patients capable of understanding the purpose and risks of the study, has been fully informed and has given written informed consent to participate in the study

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Multi- organ transplant recipients

2. Patients with serum creatinine> 200umol/l

3. Patients known to be HIV positive

4. Patients allergic or intolerant to macrolide antibiotics or tacrolimus

5. Patients with systemic infection requiring treatment, except viral hepatitis

6. Patients with severe diarrhoea, vomitting, active peptic ulcer or gastrointestinal disorder that may affect the absorption of tacrolimus

7. Patients requiring parallel therapy with immunosuppressive antibody preparations

8. Patients with any form of substance abuse, psychiatric disorder or condition which, in the opinion of the investigator, may complicate communication with the investigator

9. Patients participating or having partictpated in another clinical trial and/or those taking or having taken an investigational / non-registreteddrug in the past 28 days

10. Patients who are pregnant or breast-feeding mother

11. Patients unlikely to comply with the visits scheduled in the protocol

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2008
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-07-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1317
NTR-old	NTR1366
Ander register	: CME code is: P08.089
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A