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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22214

Source
Nationaal Trial Register

Brief title
FK 04

Health condition

kidney fuction in livertransplantation patients

Sponsors and support

Primary sponsor: MD. PhD. B. van Hoek
Source(s) of monetary or material Support: Astellas Pharma B.V

Intervention

Outcome measures

Primary outcome

- 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

Secondary outcome

- safety

- changing in mean arterial bloodpressure and number and dose of antihypertension medications usedbetween baseline(day 1) week 12 (end of C0) and week 24 (end of study)

- tacrolimus pharmacokinetics

- changing in mean lipid levels (total cholesterol, TG, HDL and LDL) and number and dose of lipid-lowering medications between Baseline (Day 1) week 12 (end of C0) and week 24 (end of study)

- tacrolimus pharmacokinetics

- subjects and graft survival

- side effects

- biopsy proven treated graft rejection

Study description

Background summary

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.

Study objective

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.

Study design

- week 0

- week 1

- week 3

- week 8

- week 12

- week 16

- week 20

- week 24

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-07-2008
Application type:	First submission

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
NTR-new	NL1317
NTR-old	NTR1366
Other	: CME code is: P08.089
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A