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A randomized multicenter trial to assess the efficacy of a combined therapy with Sirolimus (Rapamune®), MMF (Cellsept®) and corticosteroids after early elimination of cyclosporin compared to a standard immunosuppression with cyclosporin, MMF and corticosteroids in patients after kidney transplantation

Submission date 20/06/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/10/2005	**Overall study status** Completed	
Last Edited 07/07/2021	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
00/03 - A2, V 12.04.2005

Study information

Scientific Title
-

Acronym
SMART

Study objectives
Early conversion to a calcineurin-inhibitor-free protocol with Sirolimus (Rapamune®) in combination with MMF (Cellcept®) and corticosteroids is superior to a standard protocol with Cyclosporin (Sandimmun®) in combination with MMF (Cellcept®) and corticosteroids at the level of graft-function at 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Terminal renal failure

Interventions
Patients with terminal renal failure undergoing renal transplantation.

After an initial immunosuppression with Cyclosporin, MMF and Steroids for 10-24 days, patients in the study group A are converted to Sirolimus, MMF and Steroids. Patients in the control group continue on Cyclosporin, MMF and Steroids.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Serolimus (Rapamune®), MMF (Cellsept®), cyclosporin (Sandimmun®), corticosteroids

Primary outcome(s)
Graft function at 12 months defined as creatinine clearance calculated according to the Cockroft-Gault formula and serum creatinine level.

Key secondary outcome(s))
1. Incidence of biopsy proven acute rejection episodes according to Banff 97 classification
2. Patient and graft survival at 12 months
3. Incidence of treatment failure defined as:
a. Switch to another immunosuppressive regimen
b. Continuing removal of a single immunosuppressant (except MP)
c. Switch to another immunosuppressive regimen because of side effects
4. Incidence of infections
5. Incidence of malignancies
6. Incidence of new onset of hypertension
7. Incidence of side effects (e.g. metabolic disorders, others)

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Male or female patients between 18 and 60 years of age
2. Primary or secondary kidney allograft recipients (PRA <30%)
3. No requirement for dialysis since three days before randomization
4. Women of childbearing potential must have a negative qualitative pregnancy test before Sirolimus administration and agree to use a medically acceptable method of contraception throughout the treatment period and for three months following discontinuation of Sirolimus. Any woman becoming pregnant during the treatment period must discontinue Sirolimus treatment
5. Signed and dated informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Multiorgan transplant recipients
2. Cold ischemia time >36 hours
3. PRA > 30%
4. Postoperative technical complications necessitating re operation (e.g. kidney artery stenosis) or wound healing disturbances (e.g. voluminous lymphoceles)
5. Recipients of A-B-0 incompatible grafts
6. Body mass index >32
7. Patients with cardiac infarction within six months before study entry or actual unstable coronary heart disease
8. Total number of neutrophile granulocytes <1,500/mm^3 or leucocytes <2,500/mm^3 at screening
9. Patients with severe hepatic impairment (glutamic-oxaloacetic transaminase [GOT], glutamic-pyruvic transaminase [GPT], total bilirubin above three times the norm)
10. Total cholesterol >300 mg/dl and triglycerides >400 mg/dl (even under lipid lowering treatment)
11. Patients with severe intestinal disorders or other diseases significantly influencing resorption, distribution, metabolism and elimination of study medication (except diabetes) at the discretion of the investigator
12. Recipients positive for hepatitis B surface antigens or human immunodeficiency virus (HIV), organs from donors positive for hepatitis B surface antigens or HIV
13. Active malignancies within two years before study entry with the exception of squamous cell carcinoma and basal cell carcinoma of the skin
14. Patients with active systemic infections or significant coagulopathy or requirement of long term anticoagulation therapy after transplantation
15. Use of any investigational drug within four weeks before study entry
16. Known intolerability of Cyclosporine, Sirolimus, MMF or other medication required after transplantation
17. Patients with diseases which potentially could impair study performance at the discretion of the investigator
18. Pregnancy and lactation
19. Refusal to sign informed consent form
20. Patients with ongoing requirement of dialysis at time of randomization

Date of first enrolment
01/03/2005

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
Germany

Study participating centre

Dept of Surgery
Munich
Germany
81377

Sponsor information

Organisation
University of Munich - Department of Surgery (Germany)

ROR
https://ror.org/05591te55

Funder(s)

Funder type
Industry

Funder Name
Wyeth Pharmaceuticals

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/07/2010	07/07/2021	Yes	No