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Impact of a pharmaceutical care program on liver transplant patients compliance with immunosuppressive medication - A prospective, randomized, controlled trial using electronic monitoring

Submission date	Recruitment status
24/09/2007	No longer recruiting
Registration date	**Overall study status**
30/10/2007	Completed
Last Edited	**Condition category**
10/06/2021	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anja Klein

Contact details
Pharmacy Department
University Hospital Mainz
Langenbeckstr. 1
Mainz
Germany
55131

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Impact of a pharmaceutical care program on liver transplant patients compliance with immunosuppressive medication - A prospective, randomized, controlled trial using electronic monitoring

Study objectives
Pharmaceutical care provided to liver transplant patients increases compliance with the immunosuppressive medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics Committee of the Medical Association of Rheinland-Pfalz (Landesaerztekammer Rheinland-Pfalz) on 23/06/2003. (ref: 873.166.03[3828])

Study design
Prospective, randomized, controlled, single-center study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Liver transplants

Interventions
In addition to routine clinical care, patients in the intervention group receive pharmaceutical care services provided by a dedicated hospital pharmacist. The Pharmaceutical Care program usually starts about 1 week before discharge from the transplant surgery unit. The hospital pharmacist meets the patient 3 to 4 times and educates him on different issues regarding immunosuppressive medication, e.g. action of the drugs, side effects, interactions, vital signs, laboratory data and discharge medication. On the day of discharge, the hospital pharmacist

hands over and explains written information including a discharge medication plan, information regarding the immunosuppressive therapy, and a diary for documenting vital signs and laboratory data.

During the first year after transplantation, meetings with the care taking hospital pharmacist take place on a regular basis. The patient meets the pharmacist at least once every three months and maximum once per month. During these meetings the pharmacist discusses with the patient changes in medication, laboratory values and drug-related problems. Preferably, family members are involved. In addition, the hospital pharmacist reviews the patients' drug therapy, in order to assess and minimize drug related problems and simplify drug therapy.

Patients allocated to the control group receive the same medical care as the intervention group, except the direct pharmaceutical care described above.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Compliance with immunosuppressive medication measured by MEMS® for 12 months, starting at discharge.

Secondary outcome measures
1. Compliance with immunosuppressive medication measured by the following:
1.1. Pill counts, performed at each ambulatory visit
1.2. Blood levels, performed at each ambulatory visit
1.3. Questionnaires at baseline, 6 and 12 months
2. Quality of life, measured by the 36-item Short Form health survey (SF-36) at discharge, 6 and 12 months after discharge
3. Patients' knowledge regarding drug therapy, assessed by interviews using a standardized questionnaire at 2 weeks after discharge, at first ambulatory visit and 12 months after discharge
4. Patients' satisfaction with the pharmaceutical care provided, assessed by a questionnaire developed for this trial at discharge

Overall study start date
01/09/2003

Completion date
30/03/2005

Eligibility

Key inclusion criteria
1. Written informed consent
2. Age 18 years or older
3. First organ transplant
4. Follow-up care at the University Hospital Mainz for the first year after transplantation
5. Administration of oral immunosuppressive therapy as capsule or tablet
6. Literacy (German language)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
Patients who are not willing to use the Medication Event Monitoring Systems® (MEMS®)

Date of first enrolment
01/09/2003

Date of final enrolment
30/03/2005

Locations

Countries of recruitment
Germany

Study participating centre
Pharmacy Department
Mainz
Germany
55131

Sponsor information

Organisation
University Hospital Mainz, Pharmacy Department (Germany)

Sponsor details

Langenbeckstr.1
Mainz
Germany
55131

Sponsor type
University/education

Website
http://www.uni-mainz.de/FB/Medizin/Apotheke/homepage/index.html

ROR
https://ror.org/00q1fsf04

Funder(s)

Funder type
University/education

Funder Name
University Hospital Mainz (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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		27/03/2009	10/06/2021	Yes	No