

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

Submission date

24/09/2007

Recruitment status

No longer recruiting

Prospectively registered

Protocol

Registration date

30/10/2007

Overall study status

Completed

Statistical analysis plan

Results

Last Edited

10/06/2021

Condition category

Injury, Occupational Diseases, Poisoning

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

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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/00q1fsf04>

Funder(s)

Funder type

University/education

Funder Name

University Hospital Mainz (Germany)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type

[Results article](#)

Details

Date created

27/03/2009

Date added

10/06/2021

Peer reviewed?

Yes

Patient-facing?

No