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Quality Of Life and compliance after changing immunosuppression regimens

Submission date	Recruitment status	[ ] Prospectively registered
27/02/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/04/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2011	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Helge Bruns

Contact details
Department of General and Transplantation Surgery
Im Neuenheimer Feld 110
Heidelberg
Germany
69120
helge.bruns@med.uni-heidelberg.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
S-309/2010

Study information

Scientific Title
Quality Of Life and compliance after changing immunosuppression regimens: A prospective, single-centre, observational study

Acronym
QOL-LTPL

Study objectives
Quality of life and compliance is considered to be a parameter as important as postoperative outcome in modern surgery. Retard formulations have an impact on compliance and quality of life and may lead to improved adherence to therapy. Currently, immunosuppressive regimens after liver transplantation are often changed to retard formulations of immunosuppressive medication. Our hypothesis is that both quality of life and compliance improve in these patients.

To test our hypothesis, we will prospectively measure quality of life and compliance with standardised questionnaires when immunosuppressive regimens are changed to retard formulations and after three months in patients after liver transplantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Ethics Committee, Faculty of Medicine, Heidelberg University approved on 25th November 2010 (ref: S-309/2010)

Study design
Prospective single-centre observational study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Immunosuppressive regimens after liver transplantation

Interventions
In this observational study, compliance and quality of life are monitored in patients whose basic immunosuppressive regimen is changed to a once daily formulation using standardised questionnaires

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Quality of life as measured with the SF-36 health questionnaire

Secondary outcome measures
Compliance as measured with the BAASIS interview

Overall study start date
01/01/2011

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. More than or equal to 12 months after liver transplantation
2. Aged more than or equal to 18 years
3. Change in immunosuppressive regimen to a retard formulation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Intellectual or language barriers in understanding and answering the questionnaires
2. Patients admitted to the hospital

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Germany

Study participating centre
Department of General and Transplantation Surgery
Heidelberg
Germany
69120

Sponsor information

Organisation
University Hospital Heidelberg (Germany)

Sponsor details
Im Neuenheimer Feld 672
Heidelberg
Germany
69120

Sponsor type
University/education

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
University/education

Funder Name
Astellas Pharma GmbH, Munich, (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