

Quality Of Life and compliance after changing immunosuppression regimens

Submission date 27/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/04/2011	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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