ISRCTN36220396 https://doi.org/10.1186/ISRCTN36220396

Azithromycin in bronchiolitis obliterans syndrome

Submission date	Recruitment status	[_] Prospectively registered
05/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/03/2016	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-003893-46

ClinicalTrials.gov (NCT)
NCT01009619

Protocol serial number
AZI001

Study information

Scientific Title
Randomised, double-blind, placebo-controlled trial of azithromycin in lung transplantation

Study objectives
Preventive treatment with azithromycin can reduce the prevalence of bronchiolitis obliterans syndrome after lung transplantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethical Board (Commissie Medische Ethiek UZ KULeuven), 06/07/2005

Study design
Prospective interventional randomised double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bronchiolitis obliterans syndrome

Interventions
Add-on of study-drug (over-encapsulated placebo or azithromycin) to 'standard of care'. Study-drug regime: 250 mg daily for 5 days, followed by 250 mg every other day until the end of the study-period. Matching placebo regimen.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Azithromycin

Primary outcome(s)
1. Prevalence of bronchiolitis obliterans syndrome at 1 and 2 year post-transplant
2. Overall survival at 1 and 2 year post-transplant

Key secondary outcome(s))
1. Acute rejection rate at 1 and 2 year post-transplant
2. Infection rate at 1 and 2 year post-transplant
3. Evolution of pulmonary function during the first and second year after transplantation
4. Evolution of bronchoalveolar lavage (BAL) cellularity, protein levels and microbiology during the first and second year after transplantation

Completion date
28/12/2010

Eligibility

Key inclusion criteria
1. Stable LTx recipients at discharge after transplantation
2. Signed informed consent
3. Adult of either sex (aged at least 18 years old at moment of transplantation)
4. Able to take oral medication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Prolonged and/or complicated intensive care unit (ICU) course after lung transplantation
2. Early (less than 30 days post-transplant) post-operative death
3. Major suture problems (airway stenosis or stent)
4. Retransplantation (lung)
5. Previous transplantation (solid organ)
6. Multi-organ transplantation (lung and other solid organ)

Date of first enrolment
01/09/2005

Date of final enrolment
28/12/2010

Locations

Countries of recruitment
Belgium

Study participating centre
49 Herestraat
Leuven

Belgium
B-3000

Sponsor information

Organisation
Katholieke Universiteit Leuven and University Hospitals Leuven (Belgium) - Lab of Pneumology, Lung Transplant Unit

ROR
https://ror.org/05f950310

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Katholieke Universiteit Leuven and University Hospitals Leuven (Belgium) - Lab of Pneumology, Lung Transplant Unit

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	results	01/01/2011		Yes	No
Basic results				No	No