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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

EudraCT/CTIS number
2005-003893-46

IRAS number

ClinicalTrials.gov number
NCT01009619

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
1. Prevalence of bronchiolitis obliterans syndrome at 1 and 2 year post-transplant
2. Overall survival at 1 and 2 year post-transplant

Secondary outcome measures
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

Overall study start date
01/09/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.uzleuven.be/

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

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?
Basic results				No	No
Results article	results	01/01/2011		Yes	No