

Azithromycin in bronchiolitis obliterans syndrome

Submission date 05/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/03/2016	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Geert M Verleden

Contact details
49 Herestraat
Leuven
Belgium
B-3000
+32 (0)16 34 68 08
geert.verleden@uzleuven.be

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

c/o Prof Dr GM Verleden

Campus Gasthuisberg

49 Herestraat

Leuven

Belgium

B-3000

+32 (0)16 34 68 08

geert.verleden@uzleuven.be

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