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Efficacy and Safety Assessment of Azyter® (T1225) in Peri-Operative Antibio-Prophylaxis (ocular surface decontamination) for Cataract Surgery

Submission date 26/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/12/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/08/2013	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

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
2007-006228-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LT1225-PII-03/06

Study information

Scientific Title
Efficacy and Safety Assessment of Azyter® (T1225) in Peri-Operative Antibio-Prophylaxis (ocular surface decontamination) for Cataract Surgery: a pilot phase II randomised controlled trial

Study objectives
This pilot clinical study aims to evaluate the efficacy and safety of Azyter® (T1225 1.5%) versus control groups in Peri-Operative Antibio-Prophylaxis (ocular surface decontamination) for Cataract Surgery in combination of povidone iodine application and intracamerular injection with cefuroxime.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Committee for Protection of Research Subjects (Comité de Protection des Personnes [CPP]), Sud Ouest et Outre Mer 4 approved on 18/01/2008
2. Institutional Review Board (IRB), Vissum Intitute of Ophthalmology, Alicante (Vissum-Instituto de Oftalmológico de Alicante) approved on 15/01/2008

Study design
Pilot Phase II multicentre international randomised double-blind (for two groups G1 and G3) placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cataract surgery

Interventions
Test product: T1225, Azithromycin 1.5%
Group 1: T1225 1.5% eye drops for 1 day before surgery and for 2 days after surgery.
Group 2: T1225 1.5% eye drops for 3 days after surgery.

Placebo: T1225, vehicle
Group 3 : Placebo eye drops for 1 day before surgery and for 2 days after surgery.

Intervention Type
Procedure/Surgery

Phase
Phase II

Primary outcome measure
Proportion of positive cultures on the day of surgery in the three study groups.

Secondary outcome measures
1. Proportion of positive cultures at endpoint (day of surgery) depending on the sampling site.
2. Proportion of positive cultures at Day 5 after surgery.
3. Numeration of germ and of species, on Day -2, Day 0 and Day 5.

Overall study start date
22/04/2008

Completion date
25/05/2009

Eligibility

Key inclusion criteria
1. Signed and dated informed consent
2. Male or female aged from 18 to 80 years old
3. Uncomplicated cataract
4. Scheduled to undergo cataract surgery (phacoemulsification foldable intra-ocular lens surgery with injector clear corneal incision)

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
75 evaluable patients

Key exclusion criteria
Patients with the following ophthalmic conditions will be excluded:
1. Surgical conditions in the eye to be operated:
1.1. Combined surgery.
1.2. Other cataract aetiologies than senile or pre-senile cataract.
2. Non-surgical conditions in the eye to be operated:

2.1. Dacryocystitis and all others pathologies of tears drainage system.
2.2. Inflammatory ocular disease (uveitis, herpetic keratitis).
2.3. Corneal, epithelial, stromal or endothelial, residual or evolutionary disease (including corneal ulceration and superficial punctuate keratitis).
2.4. History of ocular traumatism, infection or inflammation within the last 3 months.
3. Ophthalmic condition in the contra lateral eye:
3.1. Best corrected visual acuity < 1/10.
3.2. Patient already included in the study for phakoexeresis.
3.3. History of surgical complication (notably endophthalmitis)
4. Ophthalmic condition in either eye:
4.1. Presence of glaucoma and/or ocular hypertension history.
4.2. Presence of any other ocular pathology such as dry-eye syndrome, allergy in either eye likely to require a topical treatment from Day-15 to Day 5 conjunctival sampling.

Date of first enrolment
22/04/2008

Date of final enrolment
25/05/2009

Locations

Countries of recruitment
France

Spain

Study participating centre
Service d'Ophtalmologie
Limoges
France
87042

Sponsor information

Organisation
Laboratoires Thea (France)

Sponsor details
12 rue Louis Blériot
Clermont-Ferrand
France
63017

Sponsor type
Industry

ROR
https://ror.org/04edz9p52

Funder(s)

Funder type
Industry

Funder Name
Laboratoires Thea (France)

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