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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2007-006228-36

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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.

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

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)

ROR

https://ror.org/04edz9p52

Funder(s)

Funder type

Industry

Funder Name

Laboratoires Thea (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration