

Evaluation of epithelial cell proliferative activity and fibroblasts nucleus cariometry in recurrent pterygium previously treated with mitomycin C

Submission date 12/10/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/10/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/01/2021	Condition category Eye Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Gildasio Almeida Junior

Contact details
Rua Antonio de Godoi, 3423 ap 41
São José do Rio Preto
Brazil
15015-100

Additional identifiers

Protocol serial number
Brazil - Ethics Protocol No: 003186/04

Study information

Scientific Title
Evaluation of epithelial cell proliferative activity and fibroblasts nucleus kariometry in recurrent pterygium previously treated with mitomycin C

Acronym

The Mitomycin Trial

Study objectives

This study aimed to compare the effectiveness of preventing recurrence by using MitoMycin C (MMC) by eyedrop topical administration and subconjunctival administration previous to Conjunctival Autograft Transplantation (CAT) surgery in cases of recurrence, and evaluating epithelial cell proliferation by the Ki 67 antigen as well as the evaluation of cariometry of conjunctive fibroblasts.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by FAMERP (Faculty of Medicine of São José do Rio Preto - São Paulo State) ethics committee on the 13th November 2004 (research protocol No 003186/04).

Study design

Randomised single-blind placebo-controlled cross-over study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Recurrent Pterygium

Interventions

Twenty-nine patients were randomly divided into three groups according to random numbers:
Group one: Nine patients submitted to CAT, using Placebo Eye-Drops (PED) 14 days before the surgery.

Group two: Eleven patients submitted to CAT, and administered subconjunctival injection of 0.1 ml of MMC 0.015% in the head of pterygium 30 days before surgery and PED 14 days before surgery.

Group three: Nine patients submitted to CAT, using MMC eyedrops of 0.02% 14 days before the surgery.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

MitoMycin C (MMC)

Primary outcome(s)

1. The recurrence rate after six months follow-up
2. The epithelial cell proliferative activity using as marker the antigen Ki-67
3. Fibroblasts nucleus cariometry to evaluate the area and volume of the nucleus

Key secondary outcome(s)

To evaluate the safety and efficacy of MMC used topical or subconjunctival route before the surgery treatment of pterygium

Completion date

31/08/2005

Eligibility**Key inclusion criteria**

Patients who presented symptoms of ocular irritation, photophobia and burning pain all concomitant with corneal invasion with more than 3 mm horizontal length, measured starting from the anatomical limbus.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Total final enrolment

29

Key exclusion criteria

1. Patients with:
 - a. keratoconjunctivitis sicca
 - b. Sjögren disease
 - c. vernal keratoconjunctivitis
 - d. acne rosacea
 - e. neurothrophic keratopathy
 - f. severe dysfunction of the meibomius glands; patients with meibomius gland dysfunction with clinical indications (symptoms and signs), mild to moderate, were previously treated
2. Patients that use any immunosuppressive drug, through systemic and topical administration
3. Patients aged less than 18 years of age and vulnerable groups
4. Associated glaucoma and the use of ocular hypotensor

Date of first enrolment

01/01/2005

Date of final enrolment

31/08/2005

Locations

Countries of recruitment

Brazil

Study participating centre

Rua Antonio de Godoi, 3423 ap 41

São José do Rio Preto

Brazil

15015-100

Sponsor information

Organisation

Foundation for the Support of Education and Research (Fundação de Apoio ao Ensino, Pesquisa e Extensão [FAEPE]) (Brazil)

ROR

<https://ror.org/04djvx395>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Foundation for the Support of Education and Research (Fundação de Apoio ao Ensino, Pesquisa e Extensão [FAEPE]) - FAMERP (Brazil)

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	01/07/2008	06/01/2021	Yes	No