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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/10/2006	**Overall study status** Completed	
Last Edited 06/01/2021	**Condition category** Eye Diseases	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

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

Overall study start date
01/01/2005

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

Age group
Adult

Sex
Not Specified

Target number of participants
30 patients

Total final enrolment
29

Key exclusion criteria
1. Patients with:
a. keratoconjuntivitis 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)

Sponsor details
AV Brigadeiro Faria Lima, 5416
São Pedro
São José do Rio Preo
Brazil
15090-000

Sponsor type
Hospital/treatment centre

Website
http://www.pesquisa.famerp.br/

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

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?
Results article	results	01/07/2008	06/01/2021	Yes	No