

Topical ciclosporin A eye drops for graft rejection

Submission date

06/08/2009

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

23/09/2009

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

12/04/2012

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

2000-01800

Study information

Scientific Title

Evaluation of topical ciclosporin A in prevention of corneal graft rejection: a randomised double blind single centre study

Study objectives

To evaluate the role of ciclosporin A eye drops in cases with corneal endothelial graft rejection after penetrating keratoplasty.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Indian Council of Medical Research, New Delhi, India, approved in 2001

Primary study design

Interventional

Study design

Randomised controlled double blind interventional single-centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Corneal graft rejection

Interventions

After corneal transplantation surgery, patients in the study group will receive 2% ciclosporin eye drops prepared in 1.4% polyvinyl alcohol every six hours for one year. Patients in the control group will receive 1.4% polyvinyl alcohol eye drop (placebo drops) every 6 hours for a similar duration.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ciclosporin A

Primary outcome(s)

incidence of occurrence of corneal endothelial graft rejection after high-risk keratoplasty in the study and control group at the end of one year.

Key secondary outcome(s)

1. Incidence of reversal of graft rejection in the study and control group at the end of one year
2. Incidence of occurrence possible side effects of using ciclosporin A eye drops in the study group at the end of one year

Completion date

31/01/2005

Eligibility

Key inclusion criteria

1. Patients greater than or equal to 9 years of age, either sex
2. Eyes undergoing penetrating keratoplasty
3. With two or more quadrants of corneal vascularisation extending at least 2 mm into the cornea
4. Cases of corneal re-grafts

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Grafts that are not high-risk
2. Pregnant/lactating females
3. Children below 9 years of age
4. Patients who refused to give consent

Date of first enrolment

01/08/2001

Date of final enrolment

31/01/2005

Locations

Countries of recruitment

Australia

India

Study participating centre

Centre for Eye Research Australia

Melbourne

Australia

3002

Sponsor information

Organisation

Indian Council of Medical Research (ICMR) (India)

ROR

<https://ror.org/0492wrx28>

Funder(s)

Funder type

Research council

Funder Name

Indian Council of Medical Research (ICMR) (India) (ref: 2000-01800)

Alternative Name(s)

Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, . . . , ICMR, ICMRDELHI, ...

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

India

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2010		Yes	No