

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

Prof Rasik Vajpayee

Contact details

Centre for Eye Research Australia
University of Melbourne
Royal Victorian Eye and Ear Hospital
32, Gisborne Street, East Melbourne
Victoria
Melbourne
Australia
3002
+61 (0)3 9929 8368
rasikv@unimelb.edu.au

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled double blind interventional single-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/08/2001

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

Age group

Other

Sex

Both

Target number of participants

84 patients

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)

Sponsor details

V. Ramalingaswami Bhawan

Ansari Nagar

New Delhi

India

110029

+91 (0)11 2658 8895

headquarters@icmr.org.in

Sponsor type

Research council

Website

<http://icmr.nic.in/home.htm>

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

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	01/08/2010		Yes	No