ISRCTN52781697 https://doi.org/10.1186/ISRCTN52781697

Topical ciclosporin A eye drops for graft rejection

Submission date	Recruitment status
06/08/2009	No longer recruiting
Registration date	**Overall study status**
23/09/2009	Completed
Last Edited	**Condition category**
12/04/2012	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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

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