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Corneal Transplant Follow-up Study - impact of tissue matching

Submission date	Recruitment status
23/09/2008	No longer recruiting
Registration date	**Overall study status**
06/10/2008	Completed
Last Edited	**Condition category**
30/09/2026	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

Study information

Scientific Title
Evaluation of HLA class II histocompatibility matching and cytokine polymorphisms in corneal transplantation

Acronym
CTFS II

Study objectives
Primary hypothesis:
HLA class II tissue matching between donors and recipients decreases the risk of cell-mediated rejection in high risk corneal transplants.

Secondary hypothesis:
Cytokine polymorphisms modulate the cell-mediated rejection response in high risk corneal transplants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Research Ethics Committee:
Original study approved on 11/12/1997 (ref: MREC/97/6/8)
Study extension approved on 13/9/2001 (ref: MREC/01/6/77)

Primary study design
Interventional

Study design
Multicentre prospective longitudinal study using cohort minimisation for patient allocation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Corneal transplantation

Interventions
Patients receive a corneal transplant from a donor matched for HLA class I antigens (not more than two HLA-A and/or HLA-B mismatches combined) with 0, 1 or 2 HLA class II (HLA-DR) mismatches. The level of HLA-DR mismatching defines the study group and is allocated by cohort minimisation. Data are submitted at the time of surgery and the patients are followed up at 6 months, 1, 2, 3, 4 and 5 years postoperatively. Follow-up data include whether the graft has failed, occurrence of rejection episodes, postoperative interventions and medication (including topical steroids and systemic immunosuppressives).

Intervention Type
Other

Primary outcome(s)
Time to first rejection

Key secondary outcome(s)
Time to graft failure

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Patients of any age or sex tissue typed by polymerase chain reaction using sequence-specific primers (PCR-SSP) or PCR using sequence-specific oligonucleotides (PCR-SSO) with corneal disease requiring a corneal transplant and with the following conditions that increase the risk of cell-mediated rejection:
1. Previously failed corneal transplant
2. Vascularised cornea
3. Ocular inflammatory disease
4. Bullous keratopathy consequent to previous ocular surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
1077

Key exclusion criteria
Patients requiring corneal transplants where the risk of rejection is low (e.g., keratoconus and Fuchs' endothelial dystrophy) and where there are no known pre-operative risk factors for rejection.

Date of first enrolment
01/09/1998

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Eye Hospital
Directorate of Ophthalmology

Bristol Eye Hospital
Lower Maudlin Street
Bristol
City of Bristol
England
BS1 2LX

Sponsor information

Organisation
University of Bristol (UK)

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Start-up funding: NHS Executive South & West R&D (UK) (ref: R/14/9.96)

Funder Name
Subsequent funding: National Eye Research Centre (UK) (ref: SCIAD036)

Results and Publications

Individual participant data (IPD) sharing plan
The data collected for this trial are stored and maintained by NHS Blood and Transplant (NHSBT) in the UK Transplant Registry (UKTR). Corneal transplants in the UK are routinely followed for 5 years by NHSBT and this mechanism was used for the capture of follow-up data for the CTFS II transplants at the following time points: time of transplant, then postoperatively at 6, 12, 24, 36, 48 and 60 months. The UKTR contains patient identifiable data (compliant with GDPR) and is not therefore publicly available.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/12/2020	30/09/2026	Yes	No
Basic results		27/07/2020	27/07/2020	No	No
Other publications	Baseline characteristics	01/01/2019	23/09/2019	Yes	No