ISRCTN25094892 https://doi.org/10.1186/ISRCTN25094892

# 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** |
| 27/07/2020 | 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**
N/A

# 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)

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

## 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 to request a patient information sheet

## 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

### Phase
Not Specified

### Primary outcome measure
Time to first rejection

### Secondary outcome measures
Time to graft failure

### Overall study start date
01/09/1998

### 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

### Age group
Other

### Sex
Both

### Target number of participants
1,200

### 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
England

United Kingdom

### Study participating centre
**Bristol Eye Hospital**
Bristol
United Kingdom
BS1 2LX

## Sponsor information

### Organisation
University of Bristol (UK)

### Sponsor details
Research and Enterprise Development
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH
+44 117 928 8676
Red-Office@bristol.ac.uk

### Sponsor type
University/education

**Website**
http://www.bris.ac.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

**Publication and dissemination plan**
Presentation at international eye research meetings and publication in medical journals. The study aims and design, and the donor and recipient cohort demographics have been published (see publications list).

**Intention to publish date**
01/08/2020

**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? |
|---|---|---|---|---|---|
| Other publications | baseline characteristics | 01/01/2019 | 23/09/2019 | Yes | No |
| Basic results | | 27/07/2020 | 27/07/2020 | No | No |