

Corneal Transplant Follow-up Study - impact of tissue matching

Submission date

23/09/2008

Recruitment status

No longer recruiting

Prospectively registered

Protocol

Registration date

06/10/2008

Overall study status

Completed

Statistical analysis plan

Results

Last Edited

27/07/2020

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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Contact details

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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)

Study design

Multicentre, prospective, longitudinal study using cohort minimisation for patient allocation

Primary study design

Interventional

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

Phase

Not Specified

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
Bristol
United Kingdom
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?
Basic results		27/07/2020	27/07/2020	No	No

[Other publications](#)

baseline characteristics

01/01/2019

23/09/2019

Yes

No