

Comparison of dynamic contour tonometry with Goldmann applanation tonometry for measurement of IOP in patients following penetrating keratoplasty

Submission date 29/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/06/2010	Condition category Eye Diseases	☐ 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

Protocol serial number

N0231178202

Study information

Scientific Title

Study objectives

To determine whether there is a 'significant difference' in the measurement of eye pressures in patients having had a penetrating keratoplasty (corneal transplant), by using two established methods of measurement - firstly 'dynamic contour tonometry' and secondly 'Goldmann applanation tonometry'? A 'significant difference' will be measured as greater than 2mm Hg pressure between the two methods.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Eye Diseases

Interventions

Patients who have undergone corneal transplant surgery will be contacted from a database of all patients who have undergone this surgery at Southampton Eye Unit. Patients will be asked to attend the eye clinic for one visit only. Assessments will be conducted by two of the investigators - A.Ismail (Specialist registrar Ophthalmology), and M.Lamont (Senior House Officer Ophthalmology). Each patient will have their intraocular pressure and corneal thickness measured. These measurements are routinely performed in the eye clinic and are not unduly intrusive or burdensome. In order to compare pressure measurements by DCT and GAT, the following is performed: 1) It is randomised whether DCT or GAT measurement occurs first. 2) It is also randomised which investigator will perform the measurement first. 3) Each investigator measures the patients intraocular pressure in the eye being studied alternately by GAT and DCT 3 times in succession. 4) The second investigator is blind to the readings, and performs the same measurements successively. 5) In total, the patient will have their eye pressure measured 12 times in succession. 6) The corneal thickness of the eye will be measured by ultrasound pachymetry. On average, measurement of the eye pressure by either of the methods takes roughly 5 seconds, and is completely painless. Disposable tonometer heads will be used for both instruments and between patients. There are no known complications for either technique for the patient, aside from possible inaccuracy of reading. The measurement of corneal thickness by ultrasound pachymetry is almost an identical procedure from the patients point of view. The ultrasound probe is sterilised between patients, as is normal clinical practice. Once again there are no known complications of this investigation to the patient. Once these readings have been taken, the patient is discharged from the eye clinic, back to their usual follow up. Informal discussions with patients that have been seen in the clinic with corneal transplants have shown a

positive response to research in this area, and a willingness to participate in the small added length of time to their clinic visit.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The difference in intraocular pressure measurements between DCT and GAT for each patient. 2mm Hg will be seen as significant.

Key secondary outcome(s)

Not provided at time of registration

Completion date

28/02/2006

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

30/01/2006

Date of final enrolment

28/02/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Eye Unit

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Southampton University Hospitals NHS Trust (UK) NHS R&D Support Funding

Results and Publications

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	01/07/2007		Yes	No