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

Submission date
29/09/2006

Registration date
29/09/2006

Last Edited
03/06/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Eye Diseases

[_] 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

Contact name
Mr Andre Ismail

Contact details
Eye Unit
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)7880551176
ari485-work@yahoo.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/01/2006

Completion date
28/02/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
10 patients. No controls - comparative study.

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
England

United Kingdom

Study participating centre
Eye Unit
Southampton
United Kingdom
SO16 6YD

Sponsor information

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

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

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	01/07/2007		Yes	No