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The validity and reliability of intraocular pressure measurement using rebound tonometry in young children

Submission date
11/08/2017

Recruitment status
No longer recruiting

Registration date
17/08/2017

Overall study status
Completed

Last Edited
06/11/2019

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The rebound tonometer (RBT) is used to measure eye pressure. High eye pressure can cause glaucoma leading to irreversible damage of the optic nerve in the eye, and reducing the pressure is the main treatment. Usually eye pressure is measured by the Goldman Applanation Tonometer (GAT). This method uses anaesthetic eye drops which some children dislike, resulting in the need for a general anaesthetic. The RBT device is relatively new and measures eye pressure without any anaesthetic drops. This device has a small probe that lightly touches the centre of the cornea (front of the eye) without causing any discomfort. As it is relatively new it needs to be compared with the GAT to see if it is accurate. Children tend to look upwards when eye pressures are measured, so the RBT measurement may not always be taken at the centre of the cornea. Very little is known about how this off-centre position affects the measurements, especially in young children. Connective tissue disorders like Stickler's, Alport, Ehler's Danlos and Marfan's syndromes can affect the eye. The aim of this study is to compare central and off-centre corneal readings in children with connective tissue disorders with similar readings in children with healthy eyes.

Who can participate?
Children aged between 1 month and 16 years old with glaucoma, connective tissue disease or no eye disease

What does the study involve?
One GAT reading, one on-centre and one off-centre RBT reading are taken from one randomly selected eye (or the eye with glaucoma, or healthy eye). This takes about ten minutes and is undertaken at the eye department of Birmingham Children's Hospital. Additional data concerning the children's eyes is recorded from their medical notes where possible in order to examine the influence of other factors on eye pressure such as vision, corneal thickness and curvature.

What are the possible benefits and risks of participating?
One benefit to the patient from taking part will be to look at the results of the study when they

are published to see how reliable and valid their eye pressure measurements have been. They are also given a certificate for taking part. GAT and RBT measurements are routinely undertaken in eye departments and in high street opticians and are considered to be safe methods of measuring eye pressures with no significant risk involved. Most of the children will have had their eye pressures measured before at previous visits. There is a small time inconvenience whilst the extra measurements are taken. The researchers are experienced in administering proxymetacaine eye drops to children. Proxymetacaine is the most commonly used and best tolerated anaesthetic in optometric practice. The drops can sting mildly. There is a corneal examination after the procedure to check for any corneal defects. Fluorescein is a stain used to aid the measurement of eye pressure in GAT. Adverse reactions are uncommon, but any history of previous allergic reactions is checked. Any adverse events are recorded and reported.

Where is the study run from?
Birmingham Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2015 to September 2017

Who is funding the study?
Aston University (UK)

Who is the main contact?
Prof. Leon Davies

Contact information

Type(s)
Scientific

Contact name
Prof Leon Davies

ORCID ID
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Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
186371

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1 version 4 IRAS project ID 186371

Study information

Scientific Title
The validity and reliability of intraocular pressure measurement using rebound tonometry in young children: observational cross-sectional study and case-control study

Acronym
RBT Study

Study objectives
1. GAT is considered to be the gold standard for IOP measurement. How does RBT compare with GAT in young children with glaucoma? Is RBT a good substitute for GAT for young children?
2. RBT measurements should ideally be carried out at the centre of the cornea. This is not always possible in young children. How do “off axis readings” compare with “on axis” readings for RBT in children with glaucoma?
3. How do RBT on-axis and off-axis readings in children with connective tissue disorders compare with similar readings in children with no eye disease? (No eye surgery/medication, no high prescription).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Authority North West-Liverpool East Research Ethics Committee, 23/03/2017, ref: 16/NW/0237

Study design
1. Observational cross-sectional study for questions 1 and 2
2. Case-control study for question 3

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Paediatric glaucoma, connective tissue disease

Interventions
Intraocular pressure measurement in children using the Icare rebound tonometer.
To examine the accuracy and reliability of the RBT (Aims 1, 2 and 3) the children will undergo three IOP measurements from one randomly selected eye (for aims 1 and 2 the eye with glaucoma will be selected if unilateral, for aim 3 the eye without surgery/medication and high prescription will be chosen if unilateral) as follows:
1. An on-axis GAT measurement
2. An on-axis RBT measurement
3. An eccentric RBT measurement

Measurements taken in addition to the participant's standard care will be taken by Nicola Sabokbar or Mr Joseph Abbott. Standard measurements taken as part of the participant's healthcare can be taken by members of the patients' healthcare team. If these measurements follow the study protocol, the data can be included in the study. The order of the RBT readings will be randomised wherever possible between subjects to reduce order bias. As GAT measurement can cause reduction of IOP, this will either be done last or over fifteen minutes before RBT. Where appropriate the simple randomisation technique of flipping a coin will be used to decide which eye is used and which RBT measurement is carried out first. (For aims 1 and 2 the eye with glaucoma will be selected if unilateral. For aim 3 the eye without surgery /medication and high prescription will be chosen if unilateral).

Where possible additional data will be recorded in order to examine the influence of other factors on the mean differences of the RBT measurements in question 2.

A paired sample two tailed t-test will be used to indicate whether there is a useful level of agreement between the mean of the IOP readings for GAT and on axis RBT from the 34 children with glaucoma. Individual differences between the GAT and RBT readings and their means will be calculated. Limits of agreement between GAT and RBT measurements (expressed at 95% confidence level, where the mean of the difference +/- 1.96 SD of the differences) will then be demonstrated using a Bland Altman scatter plot. This will be followed by a linear regression procedure to check for linear trend and proportional bias (agreement between the two measurements). A paired sample two tailed t-test will be used to see if the mean difference between the on axis and off axis readings is significant or not.

RBT on-axis and off-axis readings in children with connective tissue disorders and healthy children with no eye disease (no eye surgery/no eye drops/no high prescription). A repeated measures, within-between interaction ANOVA will be used to analyse whether the mean differences of the readings from the two groups are statistically significant. Further data analysis (Fisher's exact test) will be used to see if there is a statistical relationship between the additional data obtained from the participant's medical files and the mean differences of the RBT measurements in question 2.

Intervention Type
Device

Primary outcome measure
Intraocular pressure (IOP) measured in mmHg at the centre of the cornea of children with glaucoma and at 3mm temporal to the centre of the cornea by the Icare rebound tonometer. Following this, IOP is then measured by Goldman tonometer. This is undertaken within approximately 20 minutes at one visit.

Secondary outcome measures
Intraocular pressure (IOP) measured in mmHg at the centre of the cornea of healthy children and children with connective tissue disease and at 3mm temporal to the centre of the cornea by the Icare rebound tonometer. Following this, IOP is then measured by Goldman tonometer in mmHg. This is undertaken within approximately 20 minutes at one visit. The following additional data will be noted at the same time: refraction in diopters, visual acuity in LogMar, central corneal curvature in mm, central corneal thickness µm, axial length in mm, age in years.

Overall study start date
09/03/2015

Completion date
30/09/2017

Eligibility

Key inclusion criteria
1. Between 1 month and 16 years of age
2. Having eye pressure measurements as part of their care
3. Willing to have GAT and RBT measurements
4. Has glaucoma or a connective tissue disorder, or no eye disease (no eye surgery/medication, no high spectacle prescription i.e < +/- 6.00 DS and < -2.00D astigmatism)

Participant type(s)
Mixed

Age group
Child

Lower age limit
1 Months

Upper age limit
16 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Subjects who are unwilling to have GAT and RBT measurements
2. Subjects who have known allergies to proxymetacaine or fluorescein eye drops
3. Pregnant subjects
4 Babies born prematurely
5. High spectacle prescription in eyes with no disease (> +/- 6.00 DS and > -2.00D astigmatism)

Date of first enrolment
31/05/2016

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Children's Hospital
Birmingham
United Kingdom
B4 6NH

Sponsor information

Organisation
Aston University

Sponsor details
Life and Health Sciences
Aston University
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Sponsor type
University/education

ROR
https://ror.org/05j0ve876

Funder(s)

Funder type
University/education

Funder Name
Aston University

Alternative Name(s)
Aston, Aston University Birmingham UK, Aston University UK, Aston University | Birmingham, Aston University in United Kingdom, AstonUniversity

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal in October 2018. Additional documents (such as study protocol, statistical analysis plan) are available on request.

Intention to publish date
01/10/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Leon Davies.The data will be held within the Site File which will be stored securely at Birmingham Children's Hospital following the end of the study. Data will also be stored on an Aston University laptop which will be stored securely at Aston University following the end of analysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		03/03/2019	04/03/2019	No	No
HRA research summary			28/06/2023	No	No