

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

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| <b>Submission date</b><br>11/08/2017   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>17/08/2017 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>06/11/2019       | <b>Condition category</b><br>Eye Diseases         | <input type="checkbox"/> 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**  
<http://orcid.org/0000-0002-1554-0566>

**Contact details**  
Life and Health Sciences  
Aston University  
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United Kingdom  
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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  $\pm 1.96$  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  $\mu\text{m}$ , 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  $< \pm 6.00$  DS and  $< -2.00$ D 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 ( $> \pm 6.00$  DS and  $> -2.00$ D 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

Birmingham

England

United Kingdom

B4 7ET

**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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a>        |         | 03/03/2019   | 04/03/2019 | No             | No              |
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |