

# To investigate the effect of corneal biomechanical properties on rebound tonometer in patients with normal tension glaucoma

<b>Submission date</b> 08/08/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/09/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/02/2021	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English Summary

### Background and study aims

Glaucoma is an eye condition caused by a build-up of pressure within the eye (the intraocular pressure or IOP). It develops when the fluid in the eye is not able to drain properly. If untreated, it can seriously affect sight and eventually lead to blindness. Here, we want to investigate the effects of the structure and functioning (biomechanical properties) of the cornea (the transparent lens in front of the eye) on IOP measurements taken with two different types of rebound tonometry (the method used to measure IOP), the ICare ocular response analyzer (ORA) and goldmann applanation tonometry (GAT) in patients with glaucoma.

### Who can participate?

Adults aged at least 18, with or without glaucoma from the Glaucoma Clinic in the Pusan National University Hospital (South Korea)

### What does the study involve?

All participants undergo a ophthalmologic (eye) examination, and then their IOP is measured using the ocular response analyser and goldmann applanation tonometer.

### What are the possible benefits and risks of participating?

There will be no direct benefits and risks to those taking part.

### Where is the study run from?

Glaucoma clinics in Pusan National University Hospital (South Korea)

### Who is funding the study?

Initiator funded

Who is the main contact?

Dr Jonghoon Shin, jjongggal@naver.com

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Jonghoon Shin

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

The effect of corneal biomechanical properties on rebound tonometer in patients with normal tension glaucoma

### Study hypothesis

The corneal hysteresis is significantly lower and corneal-compensated IOP (IOPcc) is significant higher in normal tension glaucoma (NTG) patient than normal subjects. In addition, applanation tonometer and IOPcc may be greater in NTG than in either normal or high tension glaucoma (HTG) eyes. The null hypothesis is that the relationships between rebound tonometer and IOPcc may be different in NTG eyes with normal eyes.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Pusan National University Hospital, ref. E-2014104

**Study design**

Cross-sectional, comparative study

**Primary study design**

Observational

**Secondary study design**

Cross-section survey

**Study setting(s)**

Other

**Study type(s)**

Screening

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Condition**

Glaucoma

**Interventions**

The participants have underwent the following ophthalmic examinations : slit lamp examination, funduscopy, automated visual field examination, and IOP measurement with goldmann applanation tonometer, rebound tonometer, and ocular response analyzer

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

The corneal biomechanical factors on IOP measurements with rebound tonometer, ocular response analyzer, and goldmann applanation tonometer in both NTG patients and normal subjects

**Secondary outcome measures**

1. Agreements and reliability amongs various IOP measurements in NTG patients and normal subjects
2. Reliability and repeatability between rebound tonometer and other tonometers

**Overall study start date**

01/01/2013

**Overall study end date**

01/01/2023

# Eligibility

## Participant inclusion criteria

1. >18 years of age
2. Clear corneas and clear ocular media
3. Best corrective visual acuity > 20/40
4. Refractive error within  $\pm 5.0$  diopter of 0, and astigmatism  $\pm 3.0$ D of 0

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

160

## Total final enrolment

186

## Participant exclusion criteria

1. General condition : diabetes
2. Ocular condition : uveitis, secondary glaucoma, corneal abnormalities, nonglaucomatous optic neuropathies, previous trauma, ocular surgery or laser treatment, or any other eye diseases other than glaucoma

## Recruitment start date

01/01/2013

## Recruitment end date

01/01/2023

# Locations

## Countries of recruitment

Korea, South

## Study participating centre

179 Gudeok-ro

Busan

Korea, South

602-739

# Sponsor information

## Organisation

Pusan National University Hospital (South Korea)

## Sponsor details

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## Sponsor type

University/education

## Website

<http://bri.pnuh.co.kr/main.action>

## ROR

<https://ror.org/027zf7h57>

# Funder(s)

## Funder type

Other

## Funder Name

Initiator funded

# 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?
<a href="#">Results article</a>	results	01/01/2015	12/02/2021	Yes	No