

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

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

Plain English summary of protocol

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

Dr Ji-Woong Lee, glaucoma@pusan.ac.kr

Contact information

Type(s)

Scientific

Contact name

Dr Jonghoon Shin

Contact details

179 Gudeok-ro

Seo-gu

Busan

Korea, South

602-739

+82 (0) 512407320

jjongggal@naver.com

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 objectives

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

Health condition(s) or problem(s) studied

Glaucoma

Interventions

The participants have underwent the following ophthalmic examinations : slit lamp examination, fundoscopy, 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

Completion date

01/01/2023

Eligibility

Key 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 ± 5.0 diopter of 0, and astigmatism ≤ 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

Key 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

Date of first enrolment

01/01/2013

Date of final enrolment

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

c/o Dr Jonghoon Shin

179 Gudeok-ro

Seo-gu

Busan-si

Korea, South

602-739

+82 (0) 512407320

jjongggal@naver.com

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?
Results article	results	01/01/2015	12/02/2021	Yes	No