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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

Registration date
15/09/2014

Overall study status
Completed

Last Edited
12/02/2021

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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, 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

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 ¡À 5.0 diopter of 0, and astigmatism ¡À 3.0D 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
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Sponsor information

Organisation
Pusan National University Hospital (South Korea)

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