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Determination of corneal biomechanical properties in-vivo using a contact device

Submission date
25/06/2014

Recruitment status
Stopped

Registration date
23/07/2014

Overall study status
Stopped

Last Edited
31/03/2016

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a research project that has two studies.
Study A
A Goldmann tonometer (GAT) is the standard method used to measure the internal pressure (intraocular pressure) of the eye by pressing the cornea (the transparent dome-shaped window covering the front of the eye) with a small flat piece. The aim of Study A is to develop a new technology to measure the biomechanical (structural and functional) properties of the cornea. Characterising these properties are vital for treating conditions (e.g. diseases or injury) that effect the corneas ability to maintain its shape and its ability to focus light, and therefore effect an persons ability to see. Corneal biomedical properties also affect how some diseases (for example keratoconus, where the shape of the cornea alters to resemble a cone) are treated, the accuracy of intraocular pressure (IOP) measurements, outcome of eye surgery procedures and the design of contact lenses. Since the new device will come into contact with the eye, anaesthetic must be used before measurements are taken. Here, we want to find out how reliable the new device is and how comfortable it is to use. It is similar to a GAT tonometer, but is operated by a computer and uses a curved contact tip. The device will press against the cornea and move it inward and backward by about half of a millimetre. This will be done 3 times using different loading rates.
Study B
The aim of this study is to compare corneal stiffness and hysteresis (elastic and viscoelastic) measurements of the new device compare to those taken by another device called the Ocular Response Analyzer (ORA). The stiffness measurements will also be compared to that taken by a new non-contact device called the Corvis ST. The study will also consider the stability of the measurements when the device and the eye are not accurately aligned.

Who can participate?
The study population will be healthy volunteers and participants with raised intraocular pressure, with or without ocular hypotensive therapy. Patients will be screened against the inclusion and exclusion criteria for the study.

What does the study involve?
Participants recruited to study A will undertake the following assessments:

1. General Medical and Ophthalmic History
2. Visual Acuity Check (standard check of your vision on a letter chart)
3. Biomicroscopy, Ophthalmoscopy, Gonioscopy (standard check of the health of the eye)
4. Corneal stiffness measurements with the device under study using three different loading rates.
5. Biomicroscopy
6. A short questionnaire about comfort during the measurements
Participants recruited to study B will undertake the following assessments:
1. General Medical and Ophthalmic History
2. Visual Acuity Check (standard check of your vision on a letter chart)
3. Biomicroscopy, Ophthalmoscopy, Gonioscopy (standard check of the health of the eye)
4. Eye Pressure measurements with Goldmann applanation tonometer and dynamic contour tonometer.(These are the standard clinical methods of checking the eye pressure during a routine visit to the optometrist or eye doctor. We will need to instil one drop of a mild topical anaesthetic, which will wear off after approximately 20 minutes. You are advised to refrain from rubbing your eye until this time.).
5. Corneal Hysteresis (CH) and Corneal Resistance Factor (CRF) will be measured by the Ocular Response Analyzer (ORA).
6. Corneal force-deformation response measurements using the device.
7. The ophthalmic examination is repeated to search for any adverse effects caused by using the prototype.

What are the possible benefits and risks of participating?
Participants will volunteer to participate in this study which aims to derive the stress-strain behaviour of corneal tissue from the in-vivo stiffness measurements. Quantifying corneal mechanical properties is also important when these properties impact on the treatment of diseases such as keratoconus, accuracy of IOP measurements, improving the outcome of refractive surgery procedures and design of contact lenses.

Where is the study run from?
1. Ninewells Hospital (UK)
2. Moorfields Hospital (UK)
3. Aberdeen Royal Infirmary (UK)
The study is managed by the Liverpool Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
July 2014 to February 2015

Who is funding the study?
Engineering and Physical Sciences Research Council (UK)

Who is the main contact?
Mr M Bickerstaff
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Contact information

Type(s)
Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)
2014-002712-16

Protocol serial number
UoL000983

Study information

Scientific Title
Determination of corneal biomechanical properties in-vivo using a contact device: a single-arm, observational study

Acronym
DetCorBio

Study objectives
This is an observational study to determine the corneal biomedical properities of patients with high IOP using a novel contact device. The device applies indentation to the participants cornea and monitors the corneal deformation and load to measure the overall stiffness of the cornea. A computer is used to control the device and to store the measurements.

The cornea is a load-bearing tissue whose primary function is to focus light on the retina. The mechanical properties of the cornea are important in maintaining this function under the effect of actions such as intraocular pressure (IOP), eyelid movement and external impacts. Characterising the mechanical properties of the cornea is of critical clinical importance when action is to be taken to remedy deterioration in mechanical performance, caused for instance by disease or injury, and leading to corneal failure to maintain its shape and focus light. Quantifying corneal mechanical properties is also important when these properties impact on the treatment of diseases such as keratoconus, accuracy of IOP measurements, outcome of refractive surgery procedures and design of contact lenses

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at registration

Study design
Single-arm study of a non-CE-marked medical device

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Increased intraocular pressure of eye

Interventions
The device applies indentation to the participants cornea and monitor the corneal deformation and load to measure the overall stiffness of the cornea. A computer is used to control the device and to store the measurements.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Study B
1. The correlation between the force-displacement measurements made by the device and:
1.1. The overall stiffness as estimated mathematically based on the corneas thickness, topography and age
1.2.The differences in IOP readings made by two devices; namely the Goldmann Applanation Tonometer or GAT (which is known to be affected by corneal stiffness), and the Dynamic Contour Tonometer or DCT (which is known to be much less affected by corneal stiffness than GAT),
1.3. Corneal Resistance Factor, CRF (a stiffness-related parameter) as provided by the Ocular Response Analyzer (ORA).
1.4. The stiffness estimate provided by Corvis ST; a recently-released and not yet fully validated, non-contact device.
2. The correlation between the tissue hysteresis (difference in stress-strain behaviour under loading and unloading conditions) measured by the new device and the Corneal Hysteresis (CH) parameter provided by the Ocular Response Analyzer (ORA)
3. Estimation of tissue viscoelasticity

Key secondary outcome(s))
Study A
1. The reliability and repeatability of the device output
2. Comfort of use and tolerance of the new device
3. Assessment of general operation of device

Completion date
01/02/2015

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. At least 18 years of age
2. Normal findings in the medical history unless the investigator considers an abnormality to be clinically irrelevant
3. Normal ophthalmic findings, other than high IOP
4. Astigmatism <2D
5. Potential to complete the study and comply with appropriate instructions
6. Signature on the informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Corneal pathology or previous intra- or extra-ocular surgery, including refractive surgery (e.g., radial keratotomy, photorefractive keratotomy, LASIK, intracorneal ring), retinal surgery (e.g., buckle, photocoagulation), or implantation of a primary or secondary intraocular lens
2. Contact lens wearing within 3 days (rigid contact lenses) or 1 day (soft contact lenses) prior to study day
3. Inability to fully understand the informed consent
4. Participants who are diabetic

Date of first enrolment
01/07/2014

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Liverpool
Liverpool
United Kingdom
L69 3GH

Sponsor information

Organisation
University of Liverpool (UK)

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research organisation

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary