ISRCTN70295497 https://doi.org/10.1186/ISRCTN70295497

Frequency doubling technology, optical coherence technology and pattern electroretinogram in ocular hypertension

Submission date	Recruitment status	[_] Prospectively registered
29/06/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/04/2017	Eye Diseases	

Plain English summary of protocol

Background and study aims
Glaucoma is an eye disease that usually occurs when the fluid in the eye cannot drain properly, which increases the pressure inside the eye (ocular hypertension). This puts pressure on the optic nerve, which connects the eye to the brain, leading to damage and loss of vision (visual field loss) if not treated early. Alterations in part of the eye called the retinal nerve fiber layer are an early sign of glaucoma damage that appear before changes in the optic nerve and vision loss. Due to the irreversible nature of the damage, it is particularly important to use high-quality investigative techniques to detect the deterioration early in patients with ocular hypertension. The aim of this study is to assess three methods to see which is the most sensitive and specific for detecting early damage in ocular hypertension: optical coherence tomography (OCT), pattern electroretinogram (PERG) and frequency-doubling technology (FDT).

Who can participate?
Patients with ocular hypertension and healthy volunteers

What does the study involve?
All participants are assessed using OCT, FDT and PERG. Optical coherence tomography (OCT) is a type of scan where special rays of light are used to scan the back of your eye and produce an image of it to detect any damage to the retina (the light sensitive layer at the back of the eye) or optic nerve caused by glaucoma. FDT perimetry is a new technique for identifying visual field loss due to a sub-group of retinal ganglion cells so it is more sensitive than the normal visual field test used. PERG is a recording of the electrical activity of the nervous cells of the retina. The data from ocular hypertensive patients is compared to the data from healthy volunteers.

What are the possible benefits and risks of participating?
Participants may benefit from starting treatment to decrease their ocular hypertension when the nerve damage is just beginning and has not progressed yet. The three tests are not invasive and do not involve any risks.

Where is the study run from?
University of Bologna (Italy)

When is study starting and how long is it expected to run for?
January to November 2010

Who is funding the study?
University of Bologna (Italy)

Who is the main contact?
Dr Mauro Cellini
mauro.cellini@unibo.it

Contact information

Type(s)
Scientific

Contact name
Dr Mauro Cellini

Contact details
Via Dagnini 28
Bologna
Italy
40137
-
mauro.cellini@unibo.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FDT OH-06-10

Study information

Scientific Title
Frequency doubling technology, optical coherence technology and pattern electroretinogram in ocular hypertension: an observational study

Study objectives

Glaucoma is an optic neuropathy with the progressive loss of ganglion cells and consequent visual field alterations. The appearance of alterations in the retinal nerve fiber layer represents an early sign of glaucoma damage that precedes the changes in the optic nerve and peripheral alterations.

The quantitative investigation techniques used for the study of the retinal nerve fiber layer (RNFL) are Scanning Laser Polarimetry (SLP), Heidelberg Retinal Tomography (HRT) and, more recently, Optical Coherence Tomography (OCT). OCT makes it possible to examine high resolution cross-sections of ocular tissues using the low coherence interferometry principle and seems more reliable than SLP and HRT in the study of the RNFL.

Due to irreversible nature of the retinal ganglion cell loss and axonal damage, it is particularly important to use high quality investigation techniques for study of glaucoma patients to facilitate early detection of functional deterioration. The qualitative analysis methods currently available are Standard Achromatic Perimetry (SAP) and the more sensitive Short Wavelength Automated Perimetry (SWAP) as well as the recent Frequency-Doubling Technology (FDT) perimetry. The Pattern Electroretinogram (PERG) was introduced 25 years ago to discriminate between healthy and glaucomatous eyes as it records the electrical potentials of retinal ganglion cells and ganglion cell damage is the main cause of the decrease in visual sensitivity in glaucomatous eyes.

Study aim:
To assess which of three methods (Optical Coherence Tomography (OCT), Pattern Electroretinogram (PERG) and Frequency-Doubling Technology (FDT) is the most sensitive and specific for detecting early glaucomatous damage in ocular hypertension (OH).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee of the S. Orsola-Malpighi Hospital, Bologna, 26/06/2011, ref: FDT OH-06-10

Study design
Retrospective observational study

Primary study design
Observational

Secondary study design
Randomised controlled trial

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
Ocular hypertension

Interventions
All patients underwent:
1. An ophthalmologic examination including visual acuity and applanation IOP assessment
2. Ccorneal radius curvature measurement with automated keratometry (RK, Canon Inc., Tokyo, Japan)
3. Corneal thickness evaluation with a Tomey SP3000 pachymeter (Tomey Corp., Nagoya, Japan)
4. Biomicroscopy of the anterior and posterior segment with automatic measurement of the C/D area ratio of the optic nerve head with OCT3 (Zeiss-Humphrey, Dublin, CA).
5. Standard achromatic perimetry was also performed (SAP) with a Humphrey Field Analyzer-30.2 full threshold program (Zeiss-Humphrey, Dublin, CA)
6. Assessment of the RFNL with OCT3 (Zeiss-Humphrey, Dublin, CA)
7. Frequency-doubling technology (FDT) perimetry with RFA (Zeiss-Humphrey, Dublin, CA) 8. Pattern electrinogram (PERG) with an EREV2000 system (LACE Instruments, Pisa, Italy)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The latest generation OCT3 (Zeiss-Humphrey, Dublin, CA) was used to assess and measure the thickness of the peripapillary retinal fiber layer
2. Using the RNFL Thickness Average program, which performs three consecutive, circular scans, each one 3.4 mm in diameter centred around the optic nerve
3. The thickness of the fibers was defined as the number of pixels obtained between the anterior and posterior RNFL projection
4. The values obtained with each scan are shown in graphic form, resembling a clock face divided into four quadrants, representing the superior, nasal, inferior and temporal sections of the RNFL expressed in microns
5. Frequency-doubling technology (FDT) perimetry is a new technique designed for the rapid and effective identification of visual field impairment due to glaucoma. The FDT stimulus consists of a bar grid with a low frequency spatial sinusoidal profile (0.25 cycles/degree) subjected to a sinusoidal temporal commutation at a frequency of 25 Hz. For each visual field we evaluated the mean defect (MD) and the pattern standard deviation (PSD).
6. For PERG recording we followed ISCEV standard guideline. The PERG stimulus was a black and white checherboard of 1.6 cycles/degree with a contrast of 99%, four reversal/s and a mean luminance of 110 cd/m2. The transient PERG response was characterized by three subsequent peaks that in normal subjects are indicated on the basis of polarity and latency: N35, P50 and N95.
7. All statistical analyses were performed using the FASTAT Version 2 program package (Systat Inc., Evanston, Illinois) using the Student t test for unpaired data and Bonferroni correction, assuming $p < 0.01$ as significant
8. The Chi-square test was used for categorical data
9. The Bartlett correlation test was used to assess any correlation between thinning of the RNFL and alterations in the FDT indexes with IOP and the hemodynamic indices
10. Finally, Receiver Operating Characteristic (ROC) curve analysis was performed to determine the diagnostic sensitivity and specificity of OCT, FDT and PERG

Secondary outcome measures
Data of OCT, FDT and PERG of ocular hypertensive patients were compared to healthy controls

Overall study start date
01/01/2010

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. 52 patients aged between 44 and 76 years (mean 56±9.6), with an intraocular pressure (IOP) greater than 21 mmHg (mean 23.96±1.3)
2. A control group consisted of 55 subjects aged between 42 and 75 years (mean 54.8±10.4)

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
52 patients and 55 healthy subjects

Key exclusion criteria
1. Previous history of eye surgery
2. Previous history of ocular inflammation
3. Previous hystory of systemic diseases

Date of first enrolment
01/01/2010

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
Italy

Study participating centre
Via Dagnini 28
Bologna

Italy
40137

Sponsor information

Organisation
University of Bologna (Italy)

Sponsor details
Via Palagi, 9
Bologna
Italy
40138
+39 (0)51 34 14 50
mauro.cellini@unibo.it

Sponsor type
University/education

ROR
https://ror.org/01111rn36

Funder(s)

Funder type
University/education

Funder Name
Università di Bologna

Alternative Name(s)
University of Bologna, UNIBO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

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	01/08/2012		Yes	No