LiGHT Trial

“Health-Related Quality of Life in two treatment pathways for newly diagnosed open angle glaucoma and ocular hypertension: an unmasked, multi-centre, randomised controlled trial of initial selective laser trabeculoplasty versus conventional medical therapy”

First Investigators Meeting
29th April 2013

Chief Investigator - Mr Gus Gazzard
Research Manager - Dr Amanda Davis, Trial Optometrist - Neil Nathwani
LiGHT Trial

- Timetable for the day
  - Introduction to trial team
  - Summary of protocol
  - Status report
  - Recruitment process/ how we do it
  - What we expect from collaborating centres

- Lunch

- Hands on training
LiGHT Trial

Introduction to trial team

➢ LiGHT Team

• Gus Gazzard - Chief Investigator
• Amanda Davis - Research Manager
• Neil Nathwani - Trial Optometrist
• Haogang Zu - Post Doctoral Research Fellow
• Dominic Carrington - NIHR technician
• Charles Amoah - NIHR Technician
• Evgenia Konstantakopoulos - CLRN recruitment Optometrist
• Karine Girard-Claudon - CLRN recruitment Optometrist
LiGHT Trial

Trial Management Group

- Keith Barton, co-investigator
- Marta Buszewicz, PRIMENT triallist
- Prof David Garway-Heath, co-investigator
- Dr Rachael Hunter
- Prof Steve Morris, UCL Health Economist
- Prof Gary Rubin, co-investigator
- Richard Wormald, co-investigator
- Gareth Ambler, Lead statistician
- Catey Bunce, collaborating Statistician
- Victoria Vickerstaff, trial statistician
- Francesca Amalfitano, Research Operations Manager
- Maria Hassard, Deputy Director of R&D
- Carolyn Langford, Head of Trials Unit (RCT)
LiGHT Trial

Trial Steering Committee

- Marta Buszewicz, PRIMENT triallist
- Maria Hassard, Sponsor representative
- Prof James Morgan, independent clinician
- Susan Newell, patient representative
- Sheila Page, patient representative
- John Sparrow, Independent TSC Chair
- Luke Vale, Independent Health Economist
- Marta Van der Hoek Garcia-Finana, Independent Statistician

DMC

- Caroline Free, independent triallist
- Chris Rogers, independent trials statistician
- Independent Chair, John Salmon, glaucoma specialist
Summary of Protocol

**Background**

- Glaucoma: major problem causing visual disability and blindness but can be treated by reducing the pressure within the eye
- Adherence to medical treatment is poor, up to 75% of patients failing to use correctly
- Drop side effects limit acceptability and impair HRQL
- SLT has potential to improve HRQL substantial NHS cost saving
Summary of Protocol

Hypotheses

That for patients with ocular hypertension (OHT) or open angle glaucoma (OAG) lowering IOP with SLT as the primary treatment (‘Laser-1st’) leads to a better health-related quality of life than for those started on IOP-lowering drops as their primary treatment (‘Medicine-1st’) and that this is associated with reduced costs and improved tolerability of treatment.
Summary of Protocol

Primary:

To determine whether, in a pragmatic study that mirrors the realities of clinical decision-making, Laser-1st delivers a better HRQL at 3 years than does Medicine-1st in the management of patients with OAG and OHT.

Secondary:

- To determine whether a Laser-1\textsuperscript{st} treatment pathway:
- Costs less than the conventional treatment pathway of Medicine-1\textsuperscript{st},
- Achieves the desired level of IOP with less intensive treatment over the course of the study,
- Leads to equivalent levels of visual function after 3 years
- Is better tolerated by patients.
Summary of Protocol

Inclusion Criteria

We have used the NICE recommended thresholds for initiating treatment, with stringent diagnostic definitions of disease (OAG or OHT) for entry into the study.
Summary of Protocol

Protocol amendments

- **Gonioscopy** - (done with a high magnification lens, eg Magnaview, in a darkened room). An ‘open angle’ for the purposes of this study will be defined as *no* irido-trabecular contact (ITC) in primary position without indentation. (This is more stringent than the widely accepted definition of angle closure, i.e. 6 clock hours of ITC, in order to further minimise the risk of mis-diagnosis).

- **IOP** - trial optometrist at all centres is masked from treatment allocation or IOP is measured by an independent person who is not aware of the patient’s treatment allocation

- **Defining SLT treatment end point**
Summary of Protocol

Study assessments

- Clinical
  - Visual function, eye pressure etc

- Self reported questionnaires
  - QoL
    - Disease specific
    - Generic
  - Visual function
  - Symptom scores
Summary of Protocol

LiGHT Database

- Database is created in an online “CRF Builder”
- ‘CRF builder’ is template for Database = Data Collection Form
Summary of Protocol

LiGHT Database

- Forms correspond to a visit type e.g. Study Entry, Routine Visit, Study Exit
- CFR builder includes field rules e.g. soft/hard; range checks
Summary of Protocol

LiGHT Decision Support Algorithm

- Visual Field data uploaded as pdf into algorithm, Optical Character Recognition (OCR) extracts data
- Data compared with target.

The algorithm uses the data to:

- Stratify by disease severity
- Set a target IOP
- Suggest treatment escalation
- Recommend a follow up interval

Designed by Haogang - Post Doctoral Research Fellow
Summary of Protocol

Project Management Plan

- Six months set-up after successful ethics application
- Internal Pilot 9 months
- Total recruitment 2 years
- Follow-up 3 years
- Analysis 6 months.
Challenges ~ consequences of design

- Unmasked – how to prevent bias? Decision support software

- QoL so treatment-naive only

- Multicentre (for generalisablity) = risk of variation in intervention, Rx choices, follow-up interval etc
  - 1. Standardisation of practice = SOPs, direct observation of practice & senior clinician treatment & oversight
  - 2. Decision support software
  - 3. Stratify randomisation by centre
Challenges ~ trial management

- IT – real-time decisions needed i.e. algorithm outputs
- Database challenges – no set follow-up schedule
- Recruitment: only treatment-naive patients eligible so:
  - “screen before seen”, LiGHT Trial Stamp, education, posters in clinics and A & E, networking., being contactable, incentives to refer etc.
- Data management: 4,300+ questionnaires to send/collect/ follow-up/ check/ enter
Challenges ~ other solutions

- Data on screening process:
  - Eligible vs ineligible patients
  - Reasons for refusal
  - Consent to use data from refusing eligible

- Other resources:
  - CLRN money for recruitment assistance - optometrists
  - Trust resources – quid pro quo for clinically useful services by trial team
  - R&D resources – data management support with questionnaires
Challenges ~ insomnia issues

- What keeps me awake at night?
- Algorithm failure
- Database failure
- (recruitment targets)
- Questionnaire return rates... (& power calculations?!)
Status Report

How we are doing

LiGHT Trial - recruitment chart 2012-2014

- Actual Recruitment, April 95
- Cumulative Actual, April 110

- Monthly Target
- Cumulative Overall Target
- Actual Recruitment
- Cumulative Actual Recruitment

9 month Internal Pilot

Roll-out to all sites
Status Report

How we are doing

- LiGHT has exceeded minimum pilot requirements of 50% expected recruitment within 9 months of commencement
- with 3 months in hand: end of March 58% of expected 9 month.
### Recruitment Process

#### Scrutinising and Screening

<table>
<thead>
<tr>
<th>Month</th>
<th>Referral letters</th>
<th>Patients screened</th>
<th>Patients screened</th>
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<tbody>
<tr>
<td></td>
<td>No. of notes</td>
<td>LiGHT Potential</td>
<td>LiGHT Eligible</td>
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<tr>
<td>Oct-2012</td>
<td>72, (18)</td>
<td>76 (8 DNA)</td>
<td>10</td>
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<tr>
<td>Nov-2012</td>
<td>252, (113)</td>
<td>63 (1 DNA)</td>
<td>11 (2 referrals from A &amp; E)</td>
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<tr>
<td>Dec-2012</td>
<td>171, (61)</td>
<td>63 (9 DNA)</td>
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<tr>
<td>Jan-2013</td>
<td>308, (127)</td>
<td>95 (10 DNA)</td>
<td>15</td>
</tr>
<tr>
<td>Feb-2013</td>
<td>155, (61)</td>
<td>113 (-11 DNA)</td>
<td>18</td>
</tr>
<tr>
<td>Mar-2013</td>
<td>107, (47)</td>
<td>86 (-4 DNA)</td>
<td>11</td>
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</table>

**Key - Reasons for not taking part in the LiGHT Trial**
1- I would rather not say,
2- I would only accept laser and can’t accept being randomly chosen to have meds,
3- I would only accept meds and can’t accept being randomly chosen to have laser,
4- It’s too far to travel,
5- I feel scared about being in a study,
6- I don’t want to be a guinea pig,
7- I don’t have the time,
8- I don’t want to participate in any research,
9- The study is too long,
10- Family / friend had a bad experience,
11- Would rather see more than one clinician,
12- Other

NE = Not eligible at baseline, RNE - Randomised but not eligible
Recruitment Process

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12- Other
Recruitment Process

How we actually do it

![LIGHT Study](image)

**LIGHT Study**  
*(Laser in Glaucoma and Ocular Hypertension)*

**LIGHT Trial - Assessment check list**

<table>
<thead>
<tr>
<th>Ptn Name-ID</th>
<th>Px Arrive (if not phone contact made)</th>
<th>Informed consent taken (AT BL visit)</th>
<th>Questionnaire completed (AT BL)</th>
<th>CDR Completed</th>
<th>Algorithm Run</th>
<th>CDR entered into database</th>
<th>G.P. Letter written (if applicable)</th>
<th>LIGHT Trial G.P. Letter written (AT BL)</th>
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<tbody>
<tr>
<td>Example DNA 1</td>
<td>No - form completed</td>
<td>na</td>
<td>na</td>
<td>na</td>
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<tr>
<td>Example FU 2</td>
<td>Yes</td>
<td>na</td>
<td>na</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Example BL 3</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Version 1.0 26.03.13
Recruitment Process

How we do it

- Consent
- Randomisation

- Ensure a decision to treat has been made by a Consultant Glaucoma Specialist prior to randomization.
- Do NOT inform the patient which treatment they have been randomized to yet as this could influence the patient responses on the baseline questionnaire.
- Patients should be randomized using the more severe eye as the stratification category.
- Also, the decision to treat uni/bin-ocularly should be made prior to randomization as the treatment, SLT or Drops, should not influence whether you would treat uni/bin-ocularly.
Recruitment Process

How we do it

- Questionnaire
Recruitment Process

Assessments

BASELINE assessments for the initial trial:

Assessments:
- Consent
- Questionnaire
- Blood pressure
- Hematocrit

Assessments to book:
- Consent room
- Site lamp room
- Room
- Optometry
- Site lamp
- Site lamp room
- Site
- Site room
- Drugs
- Site prescription signed by doctor
Recruitment Process

Assessments

Follow-up assessments for the Light Trial

Assessments:  
- Visits  
- MHT  
- Visual Fields  
- Slit Lamp

Assess to book:  
- Dynamics  
- HTF Room – book Technician  
- Visual Fields room (room 23) + book Technician  
- Slit Lamp Room

PLEASE NOTE
1. Laser patient 2 week appointment – NO MHT or VF is required.
2. Follow-up IOP measurements have to be taken from someone who is needed to patient treatment allocation.
Recruitment Process

How we do it

- Treatment
  - SLT
  - Drops
- G.P Letter
- Appointment Letter
- Research team contact details
What we except from the collaborating centres

How we do it

- Recruit a minimum of 50 and maximum of 200 over 15 months
- Monthly screening log to be sent to central office
- Provide contact details of recruited patients
- Timely input of data into algorithm and database
What we except from the collaborating centres

How we do it – **tips to increase recruitment**

- Teaching to Glaucoma and A and E Departments
- Monthly News Letters- small prize
- Posters in clinic
- Web page on Hospital Website
What we except from the collaborating centres

### Screening log

<table>
<thead>
<tr>
<th>Date screened</th>
<th>No of notes screened</th>
<th>No of potential patients</th>
<th>Patient Name</th>
<th>Hospital No</th>
<th>DOB</th>
<th>LiGHT Eligible</th>
<th>Referral diagnosis</th>
<th>Diagnosis following appointment</th>
<th>Consented to trial</th>
<th>If no, reason given</th>
<th>Consented to data collection only</th>
<th>Ineligible reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun-13 e.g. 01/06/2013</td>
<td>13 notes</td>
<td>5 light potential</td>
<td>Example: Peter James</td>
<td>12345678</td>
<td>11/05/19</td>
<td>65</td>
<td>yes</td>
<td>OHT</td>
<td>OHT</td>
<td>no</td>
<td>8</td>
<td>yes</td>
</tr>
</tbody>
</table>

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1- I would rather not say  
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11- Would rather see more than one clinician  
12- Other
What we except from the collaborating centres

Centre Randomisation log

<table>
<thead>
<tr>
<th>Patient name</th>
<th>Randomisation Number</th>
<th>Date of Birth</th>
<th>Hospital Number</th>
<th>Date of randomisation</th>
<th>Randomisation arm</th>
<th>OHT/Glaucoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jo BLISS</td>
<td>GST-005</td>
<td>15/02/1952</td>
<td>167859</td>
<td>15/04/2013</td>
<td>Laser</td>
<td>OHT</td>
</tr>
</tbody>
</table>
What we except from the collaborating centres

Centre- patient contact details

<table>
<thead>
<tr>
<th>Patient name</th>
<th>Hospital No.</th>
<th>Telephone No.</th>
<th>Patient Address</th>
<th>G.P Name &amp; Address</th>
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</table>
What we except from the collaborating centres

- Timely input of data into trial algorithm and database
- Patient data should be entered into the database on day of visit: in real time if possible
- Algorithm **must** be run while the patient still present
- Patient contact details sent to co-ordinating centre on day of randomisation
LiGHT Randomisation

- Web Based online randomisation system which runs alongside the LiGHT Database
- Stratified by:
  - Site
    - Moorfields Eye Hospital NHS Foundation Trust
    - Belfast University Hospital
    - Hinchinbrook Hospital
    - Norfolk & Norwich NHS Foundation Trust
    - St Thomas’ NHS Foundation Trust
  - Diagnosis
    - OHT
    - OAG
LiGHT Randomisation

LiGHT database
Database for LiGHT Trial. Health-Related Quality of life in two treatment pathways for newly-diagnosed open angle glaucoma and ocular hypertension: an unmasked, multi-centre, randomised controlled trial of initial selective laser trabeculoplasty versus conventional medical therapy.

Your role in this trial is: Administrator.

User accounts
Notification accounts
You receive notifications for this trial.
Stop sending me notifications
Trial ID 1

LiGHT randomisation
Randomisation system for LiGHT Trial.

Your role in this trial is: Administrator.

User accounts
Notification accounts
You receive notifications for this trial.
Stop sending me notifications
Trial ID 2
LiGHT Randomisation

Already randomised patients
LiGHT Randomisation

Randomising a patient – ensure you choose the correct site and the consultants diagnosis of either OHT or OAG.

NOTE:
The more severe diagnosis is chosen
e.g. 1 - If RE is OHT and LE is OAG, you choose OAG
e.g. 2 – If RE is normal and LE is OHT, you choose OHT
Ensure all the inclusion and exclusion criteria have been met
Click continue and then confirm you are happy to proceed with the randomisation by inputting your password and clicking “Randomise”
LiGHT Randomisation

The treatment category is assigned as well as the patient identifier (Study ID).

This is the ID to be used on all study documentation and tests carried out for this patient.
LiGHT Randomisation

A file will be created in the database following randomisation.
LiGHT Algorithm + Database
## LiGHT Baseline

### ONS Educational Classification for LiGHT Trial

<table>
<thead>
<tr>
<th>Degree or equivalent</th>
<th>Higher degree</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>NQ Level 5</td>
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<tr>
<td></td>
<td>First degree/foundation degree</td>
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<td></td>
<td>Other degree</td>
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<tr>
<td></td>
<td>NQ Level 4</td>
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<tr>
<td></td>
<td>Diploma in higher education</td>
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<td></td>
<td>HNC/HND/ICT Higher diploma</td>
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<td>Teaching - Further education</td>
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<td>Teaching - Advanced education</td>
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<td>Teaching - Primary education</td>
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<td>Teaching - Foundation stage</td>
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<td>Teaching - Vocational</td>
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<td>Nursing</td>
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<td>Midwifery</td>
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<td>Other Higher education below degree</td>
</tr>
<tr>
<td></td>
<td>NQ Level 3</td>
</tr>
</tbody>
</table>

### A Level or equivalent

- Advanced Weib Indicator
- International Baccalaureate
- GNVQ/IGCSE Advanced
- A Level equivalent
- RSA advanced diploma
- ONC/OND BTEC/SCOTT/EC National level 1
- City & Guilds Advanced Cert Part 1
- S/NVQ/SVQ 9 years or more
- Single Higher equivalent
- Access qualifications
- AS-Level equivalent
- Trade Apprenticeship
- NVQ level 3 equivalent

### GCSEs grades A-C or equivalent

- NVQ level 3 equivalent
- Intermediate Weib Indicator
- GNVQ/IGCSE intermediate
- RSA Diploma
- City & Guilds Cert Part 2
- BTEC/SCOTT/EC Level 3 or General Certificate
- Over 5 GSCE grade A-C or equivalent
- No Certificate equivalent

### Other qualifications

- Foundation Weib Indicator
- GNVQ/IGCSE foundation level
- CSE/SSCE grade 1, 2, 3, 4, 5
- BTEC/SCOTT/EC First or General certificate
- S/NVQ/SVQ machine
- RSA other
- City & Guilds Foundation Part 1
- City & Guilds certificate
- Key skills qualification
- Basic skills qualification
- Entry level qualification
- Other qualification
- No qualification

---

### ONS Employment Classification for LiGHT Trial (Based on the Standard Occupational Classification 2000)

<table>
<thead>
<tr>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managers &amp; Senior Officials</td>
</tr>
<tr>
<td>Professional Occupations</td>
</tr>
<tr>
<td>Associate Professional &amp; Technical</td>
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<tr>
<td>Admin &amp; Secretarial</td>
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<tr>
<td>Skilled Trades</td>
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<tr>
<td>Personal Services</td>
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<tr>
<td>Sales &amp; Customer Services</td>
</tr>
<tr>
<td>Process, Plant &amp; Machine Operatives</td>
</tr>
<tr>
<td>Elementary Occupations</td>
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</table>
LiGHT Clinical Examinations

Visual Acuity Conversion for 4 Meter ETDRS Chart

<table>
<thead>
<tr>
<th>Viewing Distance</th>
<th>5 Meters</th>
<th>4 Meters</th>
<th>2 Meters</th>
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Visual Acuity

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CHART 2

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CCLRU GRADING SCALES

BULBAR REDNESS

LIMBAL REDNESS

LID REDNESS (area 2)

LID ROUGHNESS: WHITE LIGHT RUTTER (area 1)
LiGHT Case 1 – TEST010

DOB: 12/08/1935
Tx Category: Medicine

BASELINE (10/10/2012):

RE vis: 0.08
RE IOP: 22mmHg
RE ONH: Glaucoma
RE Rim Area: 0.77 (29um)

LE vis: -0.02
LE IOP: 19mmHg
LE ONH: Glaucoma
LE Rim Area: 0.57 (88um)
LiGHT Case 1 – TEST010

DOB: 12/08/1935  Tx Category: Medicine

BASELINE (10/10/2012):
VF Uploading – 4 point check

1. Patient ID  MEH001
2. Patient DOB  12/08/1935
3. Test Date  10/10/2012
4. MD value  RE -4.18  LE -9.32
LiGHT Case 1 – TEST010

DOB: 12/08/1935    Tx Category: Medicine

BASELINE (10/10/2012):

Stratification:

- RE Mild OAG with a target IOP of 18mmHg
- LE Mod OAG with a target IOP of 13mmHg

Prescribed G.Xalatan nocte R+L and review in 2/12
LiGHT Case 1 – TEST010

DOB: 12/08/1935      Tx Category: Medicine

PHONE ENQUIRY (29/11/2012):

• Patient having symptoms of sore itchy eyes causing discomfort R+L
• Patient has appt in 1/52 time. Advised to continue drops if possible to tolerate.
LiGHT Case 1 – TEST010

DOB: 12/08/1935  Tx Category: Medicine

FOLLOW UP No. 1 (07/12/2012):

RE vis: 0.10  LE vis: 0.04
RE IOP: 23mmHg (Target 18mmHg)  LE IOP: 18mmHg (target 13mmHg)
RE ONH: Glaucoma  LE ONH: Glaucoma
RE Rim Area: 0.78 (32um)  LE Rim Area: 0.78 (74um)
RE MD -4.11  LE MD -14.47

Mild OAG  Severe OAG (Note change in stratification due to poor VF)
Increase treatment (2nd Line)  Increase Treatment (2nd Line)

Prescribed G. Azopt BD BE (no beta blockers due to severe asthma). R/V in 2/12.
LiGHT Case 1 – TEST010

DOB: 12/08/1935  
Tx Category: Medicine

FOLLOW UP No. 2 (01/02/2013):

RE vis: 0.08  
LE vis: 0.14

RE IOP: 20mmHg (target 18mmHg)  
LE IOP: 17mmHg (13mmHg)

RE ONH: Glaucoma  
LE ONH: Glaucoma

RE Rim Area: 0.75 (39um)  
LE Rim Area: 0.57 (95um)

RE MD -5.29  
LE MD -15.39

Mild OAG  
Severe OAG

Tx continues, confirm IOP at next visit  
Increase Treatment (3rd Line)

### LiGHT Case 1 – TEST010

**DOB: 12/08/1935**  
**Tx Category: Medicine**

<table>
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<td><strong>RE vis:</strong> 0.12</td>
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<td><strong>RE IOP:</strong> 19mmHg (target 18mmHg)</td>
<td><strong>LE IOP:</strong> 14mmHg (target 13mmHg)</td>
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<td><strong>RE ONH:</strong> Glaucoma</td>
<td><strong>LE ONH:</strong> Glaucoma</td>
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<tr>
<td><strong>RE Rim Area:</strong> 0.26 (40um)</td>
<td><strong>LE Rim Area:</strong> 0.93 (81um)</td>
</tr>
<tr>
<td><strong>RE MD:</strong> -5.10</td>
<td><strong>LE MD:</strong> -18.46</td>
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</tbody>
</table>

**Mild OAG**  
**Target met**

**Cont. G. Azopt BD BE and G. Alphagan BD LE. R/V in 4/12.**
LiGHT Case 1 – Summary

- Baseline – Algorithm entry
- Baseline – Database Entry
- Visual Field uploading onto algorithm
- Medication form entry on database
- Query Closing on database
- Phone Enquiry – database entry
- Severity stratification change due to poor VF by px
- IOP check form on database
- Adverse Events entry onto database
- Switch of treatment
- GPA summary upload onto algorithm
LiGHT Case 2 – TEST020

DOB: 13/02/1964  Tx Category: Laser

BASELINE (21/11/2012):

RE vis: 0.06  LE vis: 0.12
RE IOP: 32mmHg  LE IOP: 26mmHg
RE ONH: Glaucoma  LE ONH: Glaucoma
RE Rim Area: 1.27 (25um)  LE Rim Area: 0.97 (29um)
RE MD -14.45  LE MD -9.82

Severe OAG, Target 15mmHg  Moderate OAG, Target 18mmHg
LiGHT Case 2 – TEST020

DOB: 13/02/1964  Tx Category: Laser

BASELINE (21/11/2012):
Performed SLT (R+L):
RE: #100  0.7-1.1  1.1 mode  115.08 total power
LE: #100  0.9-1.1  1.1 mode  115.12 total power

1hr post SLT IOP:
RE 42mmHg – an IOP spike of 10mmHg
LE 30mmHg – an increase in IOP of 4mmHg

Prescribed G.Iopidine 1% TDS R+L 3/7.
R/V in 1/52 (Sooner Recall)
LiGHT Case 2 – TEST020

DOB: 13/02/1964       Tx Category: Laser

FOLLOW UP No. 1 (29/11/2012):

IOP CHECK VISIT

RE vis: 0.00       LE vis: 0.06
RE IOP: 22mmHg (15mmHg target)       LE IOP: 18mmHg (18mmHg target)
RE ONH: Glaucoma       LE ONH: Glaucoma

Algorithm NOT run at 2/52 post SLT visit

IOP at a safer level, no treatment increase initiated today, review in 6/52
LiGHT Case 2 – TEST020

DOB: 13/02/1964    Tx Category: Laser

Appointment Cancellation (04/01/2013):

• Px has the flu so cannot make it to the appt. Has another operation next week and unable to come for some time.

• Rebook in 6/52
LiGHT Case 2 – TEST020

DOB: 13/02/1964  Tx Category: Laser

FOLLOW UP No. 2 (21/02/2013):

2/12 post SLT visit but 6/52 later than planned.

RE vis: 0.06  LE vis: 0.06
RE IOP: 18mmHg (15mmHg target)  LE IOP: 17mmHg (18mmHg target)
RE ONH: Glaucoma  LE ONH: Glaucoma
RE Rim Area: 1.08 (21um)  LE Rim Area: 1.27 (30um)
RE MD: -8.00  LE MD: -6.08

Monitor RE IOP. Review in 4/12. (D/W GG. If RE IOP remains high, will not RE SLT due to IOP spike and move onto medication)
LiGHT Case 2 – Summary

• Baseline – Algorithm entry (VF MD note)
• Sooner recall than planned – Database entry
• Adverse Events on SLT for IOP spike
• Algorithm NOT run at 2/52 visit
• IOP check appointment form
• Appointment cancellation
• Monitoring of IOP as between 2mmHg to 4 mmHg of target
• Deviation away from 2nd SLT due to IOP spike
LiGHT Case 3 – TEST030

DOB: 12/02/1964       Tx Category: Laser

BASELINE (28/11/2012):

RE vis: 0.24            LE vis: 0.36
RE IOP: 32mmHg          LE IOP: 34mmHg
RE ONH: Healthy         LE ONH: Glaucoma
RE Rim Area: 1.58 (11um) LE Rim Area: 1.03 (11um)
RE MD 0.62              LE MD -9.93

OHT, Target 25mmHg      Moderate OAG, Target 18mmHg
LiGHT Case 3 – TEST030

DOB: 12/02/1964  Tx Category: Laser

FOLLOW UP No.1 (12/12/2012):

IOP Check Visit

RE vis: 0.14  LE vis: 0.32
RE IOP: 22mmHg (target 25mmHg)  LE IOP: 24mmHg (Target 18mmHg)
RE ONH: Healthy  LE ONH: Glaucoma

Good IOP drop, monitor LE, review in 6/52.
### LiGHT Case 3 – TEST030

**DOB:** 12/02/1964  
**Tx Category:** Laser

#### FOLLOW UP No.2 (23/01/2013):

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<td><strong>Rim Area:</strong> 1.28 (15um)</td>
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Repeat SLT on LE. Px has work therefore booked in 1/52.
LiGHT Case 3 – TEST030

DOB: 12/02/1964

Tx Category: Laser

FOLLOW UP No.3 (15/02/2013):

2/52 post LE SLT visit

RE vis: 0.18

RE IOP: 21mmHg (target 25mmHg)

RE ONH: Healthy

LE vis: 0.12

LE IOP: 20mmHg (Target 18mmHg)

LE ONH: Glaucoma

LiGHT Case 3 – TEST030

DOB: 12/02/1964  Tx Category: Laser

FOLLOW UP No.4 (04/04/2013):

RE vis: 0.14
RE IOP: 21mmHg (target 25mmHg)
RE ONH: Healthy
RE Rim Area: 1.28 (13um)

LE vis: 0.16
LE IOP: 21mmHg (Target 18mmHg)
LE ONH: Glaucoma
LE Rim Area: 0.39 (10um)

Prescribe G.Timolol 0.25% LA LE Only. (NOT PGA due to uniocular side effects - Moroccan ethnicity). Review in 2/12.
LiGHT Case 3 – Summary

• Randomisation – Choose Severe category
• Vision/VA – SOPs
• SLT done on different day
• Justification of data
• Error in entering data
• Clinician choice of medication