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The TRIAGE Study: Identifying Non-Responders to Glaucoma Eye Drops

Submission date
28/02/2019

Recruitment status
No longer recruiting

Registration date
05/03/2019

Overall study status
Completed

Last Edited
26/10/2020

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with glaucoma have high pressure in their eyes (intraocular pressure, IOP) for which initial treatment is the administration of eye drops on a daily basis to reduce the pressure. If untreated, this high pressure can lead to blindness. When a patient with glaucoma returns to clinic and continues to have high pressure, it is unknown whether this is because of the way their eye works or because they are not using the eye drops properly. In the NHS at present, it can take many months to distinguish between those who respond to eye drops and those who do not. This is wasteful of time and medicines, as well as increasing the risk that patients develop adverse drug reactions when alternative drugs are tried, rather than addressing the true problem of adherence. We propose a new way of working (the Cardiff Model of Glaucoma Care, CMGC) which will mean, at most, two extra clinic visits (soon after being prescribed eye drops and four weeks later). At four weeks, patients will know whether their treatment works for them. After which, patients will return to their original clinic where those who do not respond to treatment will have the opportunity to discuss alternate treatment. The ultimate goal of this research is to reduce the time taken to identify whether patients respond to eye drops from a current uncertain, lengthy period of months to within four weeks, and thereby personalise eye medication to individuals with glaucoma more efficiently than is currently practiced in the NHS. The aim of this stage of the research is to develop and test the appropriateness of a new way of identifying people for whom eye drops do not work.

The research questions the study looks to address are as follows:
RQ1. Problem identification: What is the usual care for patients diagnosed with glaucoma who are about to commence eye drop treatment in Wales, in terms of identifying patients' responses to treatment?
RQ2. Development of intervention; Assessment of barriers to implementation; and Implementation and adaptation to context: Is it possible to develop and implement the Cardiff Model of Glaucoma Care (CMGC) into routine clinical practice?
RQ3. Monitoring and evaluation of implementation process and outcomes: What is the feasibility and NHS costs of implementing the CMGC?
RQ4. Monitoring and evaluation of implementation process and outcomes: Is the CMGC acceptable to patients and healthcare professionals?
RQ5. Monitoring and evaluation of implementation process and outcomes: How might CMGC

become embedded in practice? Synthesis of mixed method study findings from phases RQ1 to RQ4.

Who can participate?
RQ1: CLINICAL OBSERVATIONS, SITUATED INTERVIEWS AND SURVEY
Clinical observations and situated interviews: Healthcare professionals providing care in glaucoma clinics, alongside glaucoma patients receiving such care.
Survey: Glaucoma specialist leads (or nominated individuals) in each of the Welsh health boards: Abertawe Bro Morgannwg, Aneurin Bevan, Powys, Hywel Dda and Betsi Cadwaladr
RQ2: SOP DEVELOPMENT AND FOCUS GROUPS ON SOP
SOP development: A mixed group of key stakeholders including nurses, doctors, optometrists, orthoptists, pharmacists and patients. These members will be identified in liaison with the health boards involved with the study, as well as the International Glaucoma Association, so as to include the most appropriate parties.
Focus groups and interviews: A mixed group of key stakeholders including patients, carers, doctors, pharmacists, optometrists, orthoptists, nurses, policy makers and managers. These members will be identified in liaison with the two health boards involved with the study, as well as the International Glaucoma Association, so as to include the most appropriate parties.
RQ3: COHORT FEASIBILITY STUDY
CMGC cohort feasibility study: Glaucoma or ocular hypertension patients on the point of being prescribed eye drops will be recruited to the feasibility study across the primary research sites of Cwm Taf and Cardiff and Vale University health boards, as well as any other health boards later integrated into this phase of the study e.g. Abertawe Bro Morgannwg University health board.
CMGC staff training: Staff members for the CMGC will be comprised of doctors, nurses, optometrists or orthoptists working within either Cardiff and Vale University health board or Cwm Taf University health board, or any other health board later integrated into this phase of the study e.g. Abertawe Bro Morgannwg University health board.
RQ4: PATIENT / HEALTHCARE PROFESSIONAL INTERVIEWS AND OBSERVATION
Patient interviews: Interviews will be held with patients based within three sampling cohorts. The sampling cohorts are patients who have either i) never participated in CMGC and whom are eye drop naïve, or ii) never participated in CMGC and who are established eye drop users, or iii) participated in CMGC and are up to 4 months post-CMGC.
Healthcare professional interviews: Healthcare professionals and management team involved in the study across each of the respective health boards.
Observations: Participants for this element of the research would be those patients and healthcare professionals who provided consent to be involved for the cohort feasibility study.
RQ5. SYNTHESIS OF FINDINGS
No participants required.

What does the study involve?
RQ1: CLINICAL OBSERVATIONS, SITUATED INTERVIEWS AND SURVEY
Clinical observations and interviews: Observations will be carried out on between 30 and 50 clinical consultations across both research sites. This will involve recruiting between 30 and 50 glaucoma patients and between eight and 15 healthcare professionals for both the observation and the situated interviews.
Survey: The survey on current glaucoma practice will be issued out to all glaucoma leads based in the Welsh health boards, aside from those based in the primary research sites of Cardiff and Vale University Health Board and Cwm Taf University Health Board. This is expected to be between 5 and 12 specialists.
RQ2: SOP DEVELOPMENT AND FOCUS GROUPS ON SOP
SOP Development: The group of stakeholders for the SOP development meetings is expected to number between 10 and 12 participants in total.

Focus groups and Interviews: Four focus groups will be held, each comprising up to six to eight stakeholder members, including glaucoma patients and healthcare professionals. Based on participant availability, one-to-one and one-to-two interviews may also be conducted. This will result in a sample of between 24 and 32 participants.
RQ3: COHORT FEASIBILITY STUDY
CMGC cohort feasibility study: 60 glaucoma patients will be recruited to the feasibility study across each of the research sites. Should recruitment prove an issue to either of the first two primary research sites (Cardiff and Vale and Cwm Taf), this can be expanded to other Welsh health boards
CMGC staff training: Between four and seven healthcare professionals in each of the research sites (eight to 14 in total) will be expected to be working with the CMGC and be required to undertake training in relation to best practice from the developed SOP.
RQ4: PATIENT / HEALTHCARE PROFESSIONAL INTERVIEWS AND OBSERVATION
Patient interviews: Across the sampling cohorts, it is anticipated that between 18 and 30 glaucoma patients of varying backgrounds will be recruited to be interviewed. 6 to 10 of these will have been retained in the study following phase RQ3.
Healthcare professional interviews: It is expected that between 6 and 10 participants comprising nurses, consultants and clinic managers working within the CMGC will be recruited for these healthcare professional interviews.
Observations: It is expected that between 30 and 45 hours of observation will be carried out across all applicable research sites. This will involve between 6 and 10 healthcare professionals and between 30 and 45 glaucoma patients.

What are the possible benefits and risks of participating?
The study is unlikely to harm patients in any way as it does not involve any additional administration of medicines or treatments to those that would already be received. Indeed, the intention of the CMGC is to identify non-respondent patients and ensure they receive the appropriate care more quickly than in current practice. That said, there is the risk that patients may experience a time burden through attending the CMGC with the number of clinical attendances initially front-loaded. However, the study aims to identify any such issues as perceived by the patient, with the hope being that identifying the appropriate treatment early on outweighs any potential burdens and ultimately saves patients' time.
For NHS staff participants involved with the CMGC there will be a requirement to attend training sessions on its delivery. However, the benefits for glaucoma clinic staff in terms of gaining competence and confidence in the CMGC is felt to outweigh any of these burdens.

Where is the study run from?
The research is part of a project based at Cardiff University in the School of Healthcare Sciences and the School of Optometry and Vision Sciences. The project is led by Professor James Morgan and Professor Heather Waterman.

When is the study starting and how long is it expected to run for?
December 2017 to March 2019

Who is funding the study?
Health and Care Research Wales

Who is the main contact?
Dr. Simon Read, readsm@cardiff.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
v7; 29/01/2019

Study information

Scientific Title
Feasibility and Acceptability of a New Clinical Pathway for the Identification of Non-responders to Glaucoma Eye Drops: The TRIAGE Study

Acronym
TRIAGE

Study objectives
The research questions the study looks to address are as follows:
RQ1. Problem identification: What is the usual care for patients diagnosed with glaucoma who are about to commence eye drop treatment in Wales, in terms of identifying patients' responses to treatment?
RQ2. Development of intervention; Assessment of barriers to implementation; and Implementation and adaptation to context: Is it possible to develop and implement the Cardiff

Model of Glaucoma Care (CMGC) into routine clinical practice?
RQ3. Monitoring and evaluation of implementation process and outcomes: What is the feasibility and NHS costs of implementing the CMGC?
RQ4. Monitoring and evaluation of implementation process and outcomes: Is the CMGC acceptable to patients and healthcare professionals?
RQ5. Monitoring and evaluation of implementation process and outcomes: How might CMGC become embedded in practice? Synthesis of mixed method study findings from phases RQ1 to RQ4.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/11/2017, West Midlands - Black Country Research Ethics Committee (Village Urban Resort Dudley, 2 Castlegate Park, Birmingham Road, Dudley, West Midlands, DY1 4TB; 0207 104 8102; nrescommittee.westmidlands-blackcountry@nhs.net), ref: 17/WM/0404 (IRAS: 232242; Sponsor ref: SPON1630-17)

Study design
Non-randomised cohort feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Glaucoma / ocular hypertension

Interventions
The study is testing a new way of working in outpatient glaucoma clinics. The 'intervention' is an adaptation of the clinical appointments into two sessions separated by four weeks in which intraocular pressure (IOP) is measured and an eye drop instilled by the clinician prior to the remeasurement of the IOPs four hours post-instillation (i.e. the Cardiff Model of Glaucoma Care, CMGC)

Intervention Type
Other

Primary outcome(s)
RQ3:
3.1 The number of participants recruited
3.2 The proportion recruited from those approached
3.3 The time (in months) from clinics being open to recruit to stopping recruiting
3.4 The proportion of participants who receive the intervention as intended (i.e. receive all appropriate IOP measures, eye drops, and follow-up visits)
3.5 The number / proportion of participants who do not receive each component of the intervention
3.6 The proportion of participants who do not attend the four-week follow-up visit
3.7 The average (and some measure of variance) time taken to complete the initial visit:

3.7.1 For first-line (initial) responders
3.7.2 For second-line (initial) responders
3.7.3 For others
3.8 The proportion of participants that initiate eye drop therapy
3.9 The proportion of participants who instil eye drops as prescribed (and how this changes over the four-week period between initial and follow-up visit)
3.10 The average time interval between eye drop use (and how this changes over the four-week period between initial and follow-up visit)
3.11 The proportion of participants who discontinue eye drop therapy during this time period and time to discontinuation
3.12 The average (and measure of variance) time taken to complete the follow-up visit
3.13 The average (and measure of variance) in IOP at:
3.13.1 Baseline (prior to commencing eye drop treatments)
3.13.2 Following first-line eye drops being instilled
3.13.3 Following instilling final eye drop treatment at initial visit
3.13.4 At four weeks
In responders who adhered adequately
In responders who did not adhere adequately
In non-responders

Key secondary outcome(s))
RQ1:
1.1 Qualitative analysis (using framework analysis, FA) of a sample of consultations between patients and healthcare professionals (HCPs) to answer 'what is the usual care for patients?'
1.2 Quantitative analysis of survey designed to determine the extent to which models of care identified in (1.1) are used in Wales.
RQ2:
2.1 Qualitative analysis of focus-group and stakeholder interviews
RQ4:
4.1 Qualitative analysis (using framework analysis, FA) of interviews with patients and HCPs to answer ‘Is the CMGC acceptable to patients and HCPs?’
RQ5:
We will evaluate the study findings against the following criteria for progression to a pilot RCT of the CMGC:
5.1 40% of patients approached are recruited to the study
5.2 50% of patients receive the intervention as intended
5.3 60% of eligible patients recruited over 6 months

Completion date
31/07/2019

Eligibility

Key inclusion criteria
RQ1: CLINICAL OBSERVATIONS, SITUATED INTERVIEWS AND SURVEY
Observations and Situated Interviews:
1. Aged 18 years or over
2. Attending an outpatient glaucoma clinic
3. Diagnosed with either glaucoma, ocular hypertension, normal tension glaucoma or pseudo-exfoliative glaucoma
4. Cognitively able to participate in the study

5. Able to speak English or have access to an interpreter.
6. Healthcare professionals will be eligible for inclusion if they are providing care to patients fitting the inclusion criteria within either of the primary research sites.

Survey:
1. Glaucoma specialist lead or nominated individual in a Welsh health board aside from Cwm Taf University Health Board and Cardiff and Vale University Health Board.

RQ2: SOP DEVELOPMENT AND FOCUS GROUPS ON STANDARD OPERATING PROCEDURE
SOP Development:
1. From one of the following stakeholder groups: nurses, doctors, optometrists, orthoptists, pharmacists, and glaucoma patients.
2. Aged 18 years or over
3. Must be cognitively able to participate
4. Able to speak English.

Focus Groups:
1. From one of the following stakeholder groups: glaucoma patient, lay carer of a glaucoma patient, doctor providing glaucoma care, pharmacist, optometrist, orthoptist, nurse providing glaucoma care, policy maker or NHS manager.
2. Aged 18 years or over
3. Must be cognitively able to participate
4. Able to speak English.

RQ3: COHORT FEASIBILITY STUDY
CMGC Cohort Feasibility Study:
1. Aged 18 years or over
2. Diagnosed with either primary open angle glaucoma, ocular hypertension, pseudo-exfoliative glaucoma, IOP equal to or greater than 21 mmHg, or normal tension glaucoma
3. Be on the point of being prescribed glaucoma eye drops.
4. Must be cognitively able to participate
5. Able to speak English or have access to an interpreter.

CMGC Staff Training:
1. Healthcare professionals are required to be working in one of the two ophthalmic research sites as either a doctor, nurse, orthoptist or optometrist.

RQ4: PATIENT / HEALTHCARE PROFESSIONAL INTERVIEWS AND OBSERVATION
Patient Interviews:
1. Adult patients aged 18 years or over
2. Diagnosed with either glaucoma, ocular hypertension, normal tension glaucoma or pseudo-exfoliative glaucoma
3. Cognitively able to participate in the study
4. Have either i) never participated in CMGC and whom are eye drop naïve, or ii) never participated in CMGC and who are established eye drop users, or iii) participated in CMGC and are up to 4 months post-CMGC.

Healthcare Professional Interviews:
1. Healthcare professional or member of the management team involved in the operation of the CMGC study.

Observation:
Either:
1. Glaucoma patient receiving the CMGC intervention (aged 18 years or over) OR
2. Healthcare professional or member of the clinical team involved in the operation of the CMGC study

RQ5. SYNTHESIS OF FINDINGS
No inclusion / exclusion criteria required. No new participants.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
53

Key exclusion criteria
RQ3: COHORT FEASIBILITY STUDY
CMGC Cohort Feasibility Study:
1. Ocular surgery in the last three months
2. Having a form of acute glaucoma
3. Already being prescribed and taking eye drops
4. Any other condition that may affect drop efficacy

Date of first enrolment
01/12/2017

Date of final enrolment
15/04/2019

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

Cardiff and Vale University Health Board
Cardiff and Vale UHB Headquarters
University Hospital of Wales (UHW)
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Cwm Taf University Health Board
Royal Glamorgan Hospital
Ynysmaerdy
Llantrisant
Pontypridd
United Kingdom
CF72 8XR

Study participating centre
Abertawe Bro Morgannwg University Health Board
Singleton Hospital
Sketty Lane
Sketty
Swansea
United Kingdom
SA2 8QA

Study participating centre
Betsi Cadwalader University Health Board
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
Gwynedd
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United Kingdom
LL57 2PW

Study participating centre
Powys Teaching Health Board
Glasbury House
Bronllys Hospital
Bronllys
Powys
Bronllys

United Kingdom
LD3 0LU

Study participating centre
Hywel Dda University Health Board
Corporate Offices,
Ystwyth Building,
Hafan Derwen,
St Davids Park
Jobswell Road,
Carmarthen
United Kingdom
SA31 3BB

Study participating centre
Aneurin Bevan University Health Board
Headquarters
St Cadoc's Hospital
Lodge Road
Caerleon
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United Kingdom
NP18 3XQ

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Health Care Research Wales, Ymchwil lechyd a Gofal Cymru, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	26/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes