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Comparison between a novel device and conventional sight testing methods to determine spectacle prescription: Accuracy and speed of measurement

Submission date
23/05/2016

Recruitment status
No longer recruiting

Registration date
30/05/2016

Overall study status
Completed

Last Edited
29/11/2022

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
As the population ages, the pressure on hospital eye services is increasing. As a result, optometry-based enhanced eye care services are being developed to manage certain patient groups within the community. As their role widens, optometrists (eye doctors) spend more time on the investigation and management of eye diseases using a range of medical devices, with the measurement of the patient's glasses prescription forming an ever smaller proportion of the eye examination. This means that patients often have to change seats many times so that the different devices can be used, which requires space in the optometric clinics and a longer time for standard eye examinations. This study is going to investigate whether a novel device to measure a patient's glasses prescription, can help to save time and space in optometric clinics, while still accurately determining the glasses prescriptions. The device combines two currently used devices that measure and refine the glasses prescription, reducing the number of times the patient has to change seats during an eye examination. The aim of this study is to find out whether the novel device is an effective way of saving time and space in an optometric clinic whilst providing accurate results.

Who can participate?
Registered, returning customers aged between 13 and 45 attending the participating optometry practice for a routine eye examination that have good vision in both eyes.

What does the study involve?
All participants undergo their normal eye examination as planned. This involves measuring the time taken to assess their glasses prescription, including the time taken to move between seats placed at the different measuring devices used in the examination. Following this, participants have their prescription measured again using the novel device. The prescriptions measured using the novel device and the conventional techniques are compared, along with the time taken to determine the spectacle prescription in each case.

What are the possible benefits and risks of participating?
There are no specific benefits to participants taking part in the study. Participants will not receive payment and will have to pay for their eye examination as normal if they are a private patient. There are no known risks to being involved in the study, other than a small risk of feeling tired during the testing, but participants will be offered the opportunity for a break to minimise this risk. If a patient needs glasses, the results from the novel device being tested will not be used to determine the strength of any glasses prescribed.

Where is the study run from?
A community optometry practice located in Sale, Cheshire (UK)

When is the study starting and how long is it expected to run for?
May 2016 to September 2016

Who is funding the study?
Topcon Eye Care Company (Japan)

Who is the main contact?
Dr Catharine Chisholm
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Contact information

Type(s)
Scientific

Contact name
Dr Catharine Chisholm

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
T_SS_BEC_2016ct001

Study information

Scientific Title
Comparison of the accuracy and duration of refractive error measurements determined using a novel, semi-automated measuring device versus conventional refraction techniques, in a normal optometric population

Study objectives
The prototype device improves workflow in terms of time, space saving and patient journey, while maintaining accuracy in the measurement of refractive error, compared to the conventional methods of measuring refractive error.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre non-randomised pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Refractive error

Interventions
Participants will have their refractive error measured as part of their standard eye examination (auto-refractor and subjective refinement using a phoropter and letter chart), during which the time taken to determine their prescription will be measured.

Participants will then have their refractive error measured using the prototype device. The measurement and the time taken to determine the measurement, will be compared with the refractive result determined during the standard eye examination using conventional methods.

Intervention Type
Device

Primary outcome measure

1. Time taken to measure refractive error, including movement of participant between devices during the eye examination is measured using a stopwatch
2. Refractive outcome (sphere and cylinder) measured during the eye examination using conventional methods and with the prototype device (undertaken after the eye examination)
3. Number of times a participant must change seats is measured at the end of assessing each participant

Secondary outcome measures
1. Ease of use is rated by investigator using a questionnaire designed for the purpose of this study at the end of assessing each participant
2. Space taken up by prototype device versus conventional devices is assessed once at the start of the trial

Overall study start date
09/05/2016

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Registered, returning customers attending the optometry practice for a routine, full NHS or private eye examination, during the trial period
2. Aged betwen 13 and 45 years
3. Visual acuity (VA) in each eye better than 0.1 logarithm of the minimum angle of resolution (6/7.5) as determined from their previous records or during the eye examination

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
50

Key exclusion criteria
1. New customers attending the optometry practice for the first time
2. Patients attending for any other kind of optometric appointment other than a full eye examination
3. Those requiring significant adaptions to the standard subjective refraction process used in the eye examination, due to mental capacity/language. This includes the need to measure vision with picture or symbol charts rather than a letter chart
4. Individuals who do not exhibit normal binocular vision (ability for the two eyes to work together), including:
4.1. Subjects who report double vision as a symptom during the eye examination

4.2. Subjects who are found to have unstable binocular vision during the eye examination requiring the prescribing of exercises or prisms
4.3. Individuals with a history of lazy eye (amblyopia), suppression of vision in one eye and/or squint (turn in the eye) as recorded in their previous clinical records, or identified during the eye examination
5. Individuals with any ocular pathology or history of ocular surgery, including conditions known to affect the accuracy refraction measurements (media opacities)
6. Vulnerable subjects – will not be recruited on the basis that they would normally undergo a modified rather than the eye examination, adapted to meet their needs

Date of first enrolment
02/08/2016

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
Community optometric practice
Sale
United Kingdom
-

Sponsor information

Organisation
Topcon Eye Care Company

Sponsor details
75-1 Hasunma-cho
Itabashi-ku
Tokyo
Japan
174-8580

Sponsor type
Industry

ROR
https://ror.org/03fevzd03

Funder(s)

Funder type
Industry

Funder Name
Topcon Eye Care Company

Results and Publications

Publication and dissemination plan
No specific publication plans as this is a phase 1 trial of a prototype device and therefore the results will be used internally to guide further development work.

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Habitual Qualitative and Quantitative Physical Activity in Multi-Morbid, Older Persons with Cognitive Impairment	16/12/2020	29/11/2022	Yes	No
Other publications	feasibility sub study	13/02/2020	29/11/2022	Yes	No