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Low-dose atropine eye drops to reduce progression of short-sightedness (myopia) in children in the United Kingdom

Submission date
29/08/2018

Recruitment status
No longer recruiting

Registration date
25/10/2018

Overall study status
Ongoing

Last Edited
10/09/2024

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Short-sightedness, also called myopia, makes objects in the distance, such as the television, look blurred. This is caused by the eye growing too long, something that usually happens while children are also getting taller. People with myopia can see better with glasses or contact lenses, but this doesn't stop their eyes continuing to become more short-sighted. This study is investigating a type of eye drop called atropine that might help to stop myopia getting worse as children get older. The aim of this study is to assess the effectiveness and safety of low dose atropine (0.01%) eye drops to reduce the progression of myopia in UK children.

Who can participate?
Children aged 6-12 years with myopia (short-sightness) of -0.50 diopters (D) or greater in both eyes

What does the study involve?
Eye drops that contain an ingredient (atropine) are compared against eye drops that are only designed to keep eyes moist (referred to as placebo eye drops) to see if they help slow down the progression of myopia. Participants are randomly allocated to use either the atropine or placebo eye drops. Participants, their parent(s)/guardian(s) and the researchers at the clinic do not know which eye drops participants are receiving. Most children in the study get the atropine eye drops (193 children) and a smaller number (96 children) get the placebo eye drops. Participants need to put one drop into each eye once daily for 24 months, during this time participants also attend the clinic every 6 months for assessments (eye tests) and to complete questionnaires to find out about their general health, daily activities (screen time and time spent outside) and how they find using the eye drops.

What are the possible benefits and risks of participating?
For children receiving the atropine eye drops, their myopia may not progress as quickly as it would have done without the eye drops. High levels of myopia can increase the risk of developing other conditions in adulthood, such as maculopathy, retinal detachment and glaucoma, so it is beneficial to keep the levels of myopia as low as possible. There are no

particular benefits to children receiving the placebo drops. The eye drops used in this study are expected to be safe and well tolerated. Both atropine and placebo drops have been used in eye care for many decades around the world. Atropine has been used for many years by children in Asia (e.g. China and Singapore) as a treatment to slow the rate of their myopia progression. The following side effects are possible from using the eye drops in this study: the eye drops may sting a little, pupil size may increase (which may make it a little uncomfortable in bright light), and ability to focus on very close up objects may be reduced. Other less common and rare side effects of atropine include eyes feeling a bit uncomfortable or looking a bit red, an increase in the pressure inside the eye and mild swelling of the eyelids. All participants and their parent(s) /guardian(s) will be provided with information describing what to look out for so that you can take action if they have any worries.

Where is the study run from?
Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?
October 2017 to May 2027

Who is funding the study?
National Institute for Health Research (NIHR) Efficacy and Mechanism Evaluation (EME) Programme

Who is the main contact?
1. Paul Doherty
CHAMP-UK@nictu.hscni.net
2. Prof. Augusto Azuara-Blanco

Study website
https://nictu.hscni.net/service/champ-uk/

Contact information

Type(s)
Scientific

Contact name
Prof Augusto Azuara-Blanco

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Additional identifiers

EudraCT/CTIS number
2017-004108-23

IRAS number
220664

ClinicalTrials.gov number
NCT03690089

Secondary identifying numbers
17097AB-AS

Study information

Scientific Title
Low-dose atropine eye drops to reduce progression of myopia in children: a multi-centre placebo-controlled randomised trial in the United Kingdom

Acronym
CHAMP UK

Study objectives
Low dose atropine eye drops will reduce myopia progression in children compared with placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 22/07/2019:
Approved 02/10/2018, Health and Social Care Research Ethics Committee B (HSC REC B) (ORECNI Office, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn, BT28 2RF; +44 028 95361400; RECB@hscni.net), ref: 18/NI/0164

Previous ethics approval:
Health and Social Care Research Ethics Committee B (HSC REC B), ref: 18/NI/0164 - approval pending

Study design
Multicentre randomised double-masked placebo-controlled superiority trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, University/medical school/dental school

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Myopia

Interventions
All eligible participants who agree to join the study will be randomised using Sealed Envelope, ensuring allocation concealment. A total of 289 participants will be recruited with an allocation ratio of 2:1 (193 atropine: 96 placebo).

The intervention group will receive 0.01% atropine sulfate eye drops, while the control group will receive placebo eye drops. Both groups will be enrolled into the study and receive eye drops to be administered into each eye once daily for 24 months. During this time each participant will attend the clinic every 6 months for assessments to determine the progression of their myopia and to complete some questionnaires relating to their general health and how they find using the eye drops. They will also be provided with an activities questionnaire to complete at home to determine how long they spend outdoors and their daily screen time. At each visit participants will also receive their 6-month supply of their eye drops.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Atropine

Primary outcome measure
Spherical equivalent refractive error (i.e. myopia severity) of both eyes measured by autorefractor under cycloplegia (adjusted for baseline) at 24 months

Secondary outcome measures
All secondary outcome measures will be assessed at 24 months:
1. Central axial length, measured using a laser biometer at central fixation conditions
2. Best corrected distance visual acuity (BCdVA) (uniocular and binocular), assessed using the logMAR ETDRS chart
3. Near visual acuity (uniocular and binocular), tested using near logMAR ETDRS at 40 cm
4. Reading speed, measured with the Wilkins Rate of Reading test
5. Pupil diameter, measured using an autorefractor
6. Accommodation, measured prior to the instillation of cycloplegia using the autorefractor
7. Spectacle correction, from current prescription
8. Tolerability, measured using a 4-point scale to quantify, from the point of view of the participant, (1) local irritation/stinging associated with eye drop instillation; (2) photophobia; and (3) difficulties reading and writing
9. Adverse event rates and allergic reactions rates, determined through reported events
10. Quality of life, measured using the EQ-5D-Y

The CHAMP UK trial will also be exploring the following exploratory outcomes/mechanistic evaluations;
1. Peripheral axial length, measured using a laser biometer at peripheral fixation conditions
2. Peripheral retinal defocus, measured with the autorefractor at central and peripheral fixation conditions
3. Anterior chamber depth, measured with a laser biometer
4. Iris colour, measured using a visual grading scale of dark brown, light brown, blue, green, grey
5. Height, measured in cm
6. Weight, measured in kg
7. Hours of outdoor activity, measured using an activities questionnaire
8. Ciliary body biometry, measured using anterior-segment OCT (AS-OCT)
9. Chorio-retinal thickness, measured using spectral domain OCT (SR-OCT)

Overall study start date
01/10/2017

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Aged 6-12 years (at the time of consenting)
2. Myopia of -0.5D or greater (spherical equivalent refractive error) in both eyes
3. Best-corrected distance visual acuity (BCDVA) 0.20 logMAR or better in both eyes

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
289

Key exclusion criteria
1. Children with other ocular morbidities
2. Myopia of -10D or greater in either eye
3. Astigmatism of 2D or higher in either eye
4. Amblyopia
5. Significant health problems that can compromise the ability to attend research visits or

complete the trial
6. Other factors that may compromise the ability to attend the research appointments
7. Parents or children with poor understanding of the English language
8. Children enrolled in other interventional trials
9. Allergy or hypersensitivity to atropine or excipients

Date of first enrolment
03/04/2019

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Study participating centre
Northern Ireland Clinical Research Facility
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Aston University
School of Life and Health Sciences
Birmingham
United Kingdom
B4 7ET

Study participating centre
Centre for Living
Glasgow Caledonian University
Cowcaddens Road
Glasgow
United Kingdom
G4 0BA

Study participating centre
Anglia Ruskin University Eye Clinic
Bradmore Street
Cambridge
United Kingdom
CB1 1BD

Study participating centre
Belfast Health and Social Care Trust
The Royal Group of Hospitals
274 Grosvenor Rd
Belfast
United Kingdom
BT12 6BA

Study participating centre
Birmingham Children's Hospital
43 Clarence Road
Harborne
Birmingham
United Kingdom
B17 9LA

Study participating centre
Royal Hospital for Children
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Cambridge University Hospitals
Addenbrookes Hospital, Box 41
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Belfast Health and Social Care Trust

Sponsor details
2nd Floor
King Edward Building
Royal Victoria Hospital
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net/

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Efficacy and Mechanism Evaluation Programme

Alternative Name(s)
NIHR Efficacy and Mechanism Evaluation Programme, EME

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/05/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Azuara-Blanco (Chief Investigator). Requests will be reviewed on a case by case basis by the Chief Investigator and Trial Management Group. The data from this trial will be shared with The Dublin Institute of Technology and Lions Eye Institute, Western Australia to facilitate prospective individual participant data meta-analysis with the MOSAIC trial (ISRCTN36732601) and the WA ATOM trial (ACTRN12617000598381) once the results of the CHAMP UK trial are accepted for publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/07/2020	05/05/2023	Yes	No
HRA research summary			28/06/2023	No	No