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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
29/08/2018		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/10/2018 Last Edited	Ongoing Condition category	Results		
		Individual participant data		
14/08/2025	Eye Diseases	[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. Lynn Murphy
CHAMP-UK@nictu.hscni.net

2. Prof. Augusto Azuara-Blanco

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS) 2017-004108-23

Integrated Research Application System (IRAS)

220664

ClinicalTrials.gov (NCT)

NCT03690089

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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)

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

12 years

Sex

All

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

18/02/2022

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

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

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, Efficacy and Mechanism Evaluation (EME), EME

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes