Investigator led, double-masked, multicenter, randomized clinical trial for the comparison of Atropine 0.5% versus Atropine 0.05% eye drops for the prevention of myopia progression in Dutch children.

Published: 07-07-2022
Last updated: 25-09-2024

This study has been transitioned to CTIS with ID 2024-516379-34-00 check the CTIS register for the current data. Objectives:To compare the efficacy of Atropine 0.05% to Atropine 0.5% treatment in European children with progressive myopia, and to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON55937

Source
ToetsingOnline

Brief title
MAD trial: Myopia Atropine Dose

Condition

- Vision disorders

Synonym
Myopia, nearsightedness

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw (NWO)

Intervention

Keyword: Atropine, Axial length, Child, Myopia

Outcome measures

Primary outcome

To compare the efficacy of atropine 0.05% to atropine 0.5% treatment against progression of AL in children with progressive myopia.

Secondary outcome

Secondary study parameters/outcome:

• To compare the efficacy of atropine 0.05% to atropine 0.5% treatment against progression of SER (Spherical Equivalent of Refraction) in children with progressive myopia.

• To evaluate the safety, adherence, and reasons for nonresponse of atropine 0.05% compared to atropine 0.5% treatment.

• To create an online BIG DATA registry for myopia treatment in the Netherlands which can be used for evaluation of myopia progression in the long term.

• To evaluate the rebound effect after treatment-stop.

Study description

Background summary

Protocol bladzijde 6:

Rationale: With the current worldwide myopia boom the frequency of high myopia will also increase, and potentially blinding complications such as myopic macular degeneration, retinal detachment, and glaucoma will occur more often. In the Netherlands high myopia will become the most important cause of low vision and blindness by 2050. As treatment options are limited once the eye is fully grown, prevention of a long axial length at childhood is the only way to counteract this prospect. Pharmacological interventions have shown a high efficacy in stopping eye growth, in particular eye drops with high dose Atropine (0.5%, 1%). Nevertheless, the high frequency of side effects (photophobia, reading problems) of these Atropine concentrations has favoured the use of low dose Atropine. Atropine 0.01% is the most commonly used and lowest dosage; it has shown stability of refractive error, but not of axial length. Recent studies have shown that Atropine 0.05% has low risk of side effects, but a higher efficacy than 0.01%. Many ongoing trials are now comparing various low dose Atropine to placebo, but none are comparing the highest low dose to the lowest high dose Atropine.

Study objective

This study has been transitioned to CTIS with ID 2024-516379-34-00 check the CTIS register for the current data.

Objectives:
To compare the efficacy of Atropine 0.05% to Atropine 0.5% treatment in European children with progressive myopia, and to evaluate the safety, adherence, and reasons for nonresponse.
To create an online BIG DATA registry for myopia treatment in the Netherlands which can be used for evaluation of myopia progression in the long term.

Study design

Study design: Investigator led, double-masked, multicentre, randomized clinical trial

Intervention

Intervention: Comparison of 0.05% Atropine to 0.5% Atropine in a multicentre study with a 3 year duration, followed by a 2 year observational period.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Prior research with high dose Atropine (0.05%) revealed a significant slowing of myopia progression in school-age children, while minimal effects were identified for low dose (0.01%). There is a 50:50 chance for a given child to be randomized to high dose Atropine. There is a

small risk that side effects may occur while using low dose Atropine. For much higher doses of approved Atropine Sulfate eye drops (1%) used in both North America & the EU, side effects reported in previous studies of high-dose Atropine eye drops include: Eye discomfort, glare, blurred near vision, light sensitivity, pain and stinging at time of drop, inflammation of the cornea (clear layer on the front of the eye), dry eye, redness and swelling of the eye or eyelid, irritability, fast heartbeat, restlessness and dryness of skin, mouth or throat. While the risk of such side effects listed above are much less for the dilute Atropine (0.01% & 0.5%) eye drops being studied in this protocol, children may experience other risks or side effects of Atropine eye drops that are currently unknown. Multifocal photochromic glasses will be provided to solve blurred near vision and light sensitivity in high dose Atropine (0.5%).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children aged 6 to <11 years
Onset of myopia >=4 years of age
Spherical Equivalent Refraction (SER) of at least -1.00 D and no greater than -6.00 D in each eye
Intraocular pressure <21 mm Hg in each eye

Exclusion criteria

Allergy to Atropine
History of amblopya or strabismus
History of retinal dystrophy or systemic order
Prior myopia control treatment (Atropine, ortho-keratology, multifocal contact lenses).
Glaucoma

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-12-2022
Enrollment:	550
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Atropine
Generic name:	Atropine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	07-07-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-11-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-01-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-03-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-04-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	31-10-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-01-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-05-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-07-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2024-516379-34-00
EudraCT	EUCTR2021-004015-11-NL
CCMO	NL78526.078.21