The influence of dropsize of tropicamide 0.5% eyedrops on pupildilation

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Primary:Is the degree of pupildilation, achieved after administrating a 4.5 microliter microdrop tropicamide 0.5% equivalent to the pupildilation after a regular 30 microliter eydrop tropicamide 0.5% in healthy volunteers?Secondary: Is there a...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39681

Source
ToetsingOnline

Brief title
MICRO1

Condition

- Other condition

Synonym
no disease: pupil diagnostics

Health condition

geen aandoening; betreft een diagnosticum in de oogheelkunde

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Eigen gelden St.Elisabeth Ziekenhuis

Intervention

Keyword: Eyedrops, Microdrops, Mydriasis, Tropicamide

Outcome measures

Primary outcome

Within-subject pupildilation (compared to baseline) of a regular eyedrop and a

microdrop at t=40 min.

Secondary outcome

Physical discomfort, experienced after administration of a microdrop and a

regular eyedrop.

Qualitative evaluation of the mydriatic reponse/time curves of both the

microdrop and the regular eyedrop.

Study description

Background summary

Currently used eyedrops sometimes cause significant ocular and systemic adverse reactions. Using regular eyedrops, it has been shown that a higher dose is administrated than necessary to obtain a sufficient pharmacologic response. Most of the dose is immediately removed from the eye. Adverse reactions are mostly dose-dependent. From this is hypothesized that a microdrop and a regular eydrop may be equally effective, while adverse reactions are possibly minimised by reducing eyedrop size.

Study objective

Primary:Is the degree of pupildilation, achieved after administrating a 4.5 microliter microdrop tropicamide 0.5% equivalent to the pupildilation after a regular 30 microliter eydrop tropicamide 0.5% in healthy volunteers?

Secondary: Is there a subjective difference in the degree of physical discomfort, experienced after administration of a microdrop compared to a regular eyedrop?
Qualitative evaluation of the mydriatic reponse/time curves of both the microdrop and the regular eyedrop.

Study design

Randomised, single-blind cross-over pilotstudy

Intervention

Subjects are randomly assigned to one of two interventiongroups. Subjects in group A receive a microdrop in both eyes on day 1, group B receive a regular eyedrop. Pupilsize measurements are performed 10 times during a 2 hour timeframe. The second testing session is planned after at least 7 days. Group A receives a regular drop, group B a microdrop and the measurements are repeated.

Study burden and risks

Subjects may experience short-term physical discomfort as a result of the intervention of this study. A transient burning sensation may occur after administration of the eyedrop. Also, subjects may have a blurred vision while the pupil is dilated.
Limited risk exists in developing narrow-angle glaucoma after administration of tropidamide, as well as a small risk of hypertension or tachycardia. These risks are diminished by performing a medical examination. Subjects having risk factors are excluded from this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age between18-64 years
informed consent

Exclusion criteria

eye disease, risk factors for angle-closure glaucoma, previous eyetrauma/surgery, dioptric value >+6, cardiac disease, diabetes, medication for the eye, medication influencing pupildiameter, substance abuse, (possible) pregnancy, breastfeeding

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2013
Enrollment:	28
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Tropicamide
Generic name:	Tropicamide
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	19-12-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	17-01-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	10-06-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	27-06-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
EudraCT	EUCTR2012-005219-18-NL
CCMO	NL42717.008.12