Administration of Topical Ophthalmic Medication (ATOM): Feasibility of the spraynozzle technique.

Published: 19-04-2012
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To demonstrate proof of concept, i.e. equivalent dispersal by both methods.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37543

Source
ToetsingOnline

Brief title
ATOM

Condition

- Other condition

Synonym
n.v.t.

Health condition

n.v.t. onderzoek wordt verricht op gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Medspray XMEMS BV
Source(s) of monetary or material Support: Ministerie van Economische Zaken;Landbouw en Innovatie;Provincies Gelderland en Overijssel;Medspray XMEMS BV

Intervention

Keyword: eye drops, fluoerscein, ophthalmic spray

Outcome measures

Primary outcome

Autofluorescence.

Secondary outcome

Treatment satisfaction score

Blinking reflex (qualitative assessment by investigator).

Study description

Background summary

Eye drops are frequently used for opthalmic drug delivery. An alternative method by means of an ophthalmic spray device, ADE Fluorescein A, has been developed for improved efficiency and convenience.

Study objective

To demonstrate proof of concept, i.e. equivalent dispersal by both methods.

Study design

Proof of concept, pilot study.

Intervention

Topical ocular administration of fluorescein by 1) conventional eye drops in one eye versus 2) ADE Fluorescein A in the fellow eye.

Study burden and risks

Participation requires a single visit to the Rotterdam Eye Hospital which takes about two hours. Participants do not benefit. Risks of topical fluorescein are considered to be low. Autofluorescence measurement is a non-invasive procedure. Burden is moderate.

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

Healthy volunteers with healthy eyes.
Informed consent.

Age > 18 years.

Exclusion criteria

Allergy/hypersensitivity for fluorescein.
Previous ocular surgery, including refractive laser surgery.
Corneal condition (e.g. Sjögren, punctata).
Contact lens wear.
Active epithelial HSV keratitis.
Pregnancy.;Concurrent use of eye drops.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2012
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	ophthalmic spray device;ADE Fluorescein A
Registration:	No

Ethics review

Approved WMO Date:	19-04-2012
Application type:	First submission
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
CCMO	NL39567.078.12