A tilt-detector for the Xal-Ease eye drops delivery aid. Usability and patient satisfaction.

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Part 1: To determine the effectiveness of self-instillation of fluorescein drops by means of the combined E-Box/Xal-Ease device. Part 2: To determine patient satisfaction of the two administration procedures, i.e. Xal-Ease versus E-Box/Xal-Ease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON32758

Source
ToetsingOnline

Brief title
E-Box & Xal-Ease

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma/ocular hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Pfizer,Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Keyword: Delivery aid for eye drops, Glaucoma/Ocular hypertension, Patient satisfaction

Outcome measures

Primary outcome

Part 1: Ratio of correctly administered fluorescein drops.

Part 2: Treatment satisfaction score.

Secondary outcome

IOP

Study description

Background summary

Glaucoma is a chronic and progressive disease requiring long-term treatment. Self-instillation of eye drops poses a risk of limited compliance, especially in the elderly, which affects both health outcome and costs of glaucoma care. Failure of proper instillation of eye drops can be caused by the incorrect (vertical) positioning of the bottle relative to the eye. The delivery aid for Xalatan® (i.e. the Xal-Ease) has been adapted with an auxiliary tool, the E-Box, comprising a tilt-sensor. The E-Box measures the angle relative to gravity and provides both an auditory and a visual signal to press the bottle when positioned correctly.

Study objective

Part 1: To determine the effectiveness of self-instillation of fluorescein drops by means of the combined E-Box/Xal-Ease device.
Part 2: To determine patient satisfaction of the two administration procedures, i.e. Xal-Ease versus E-Box/Xal-Ease.

Study design

Part 1: Diagnostic.
Part 2: Open-label, cross-over pilot study.

Study burden and risks

The E-Box does not pose any risk. Possibly, compliance will be improved during use of the E-Box. Participation requires three extra, study-related, visits to the Rotterdam Eye Hospital, with each visit taking about 20 minutes.

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

- Informed consent.
- Age > 18 years.
- Glaucoma or ocular hypertension.
- Use of Xalatan for IOP reduction.

Exclusion criteria

- IOP reducing surgery.
- Auditory impairment.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-02-2010
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	NL30864.078.09