Adherence improvement in glaucoma patients

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To study the effect on intraocular pressure in patients using the Travalert dosing aid with or without the additional use of the Eyot and with of without additional patient education.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Interventional

Summary

ID

NL-OMON31300

Source
ToetsingOnline

Brief title
Adherence-Travalert

Condition

- Glaucoma and ocular hypertension

Synonym
Glaucoma, ocular hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Alcon Laboratories
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Adherence, Glaucoma, Intraocular pressure, Travalert

Outcome measures

Primary outcome

Primary endpoint is the intraocular pressure measured at the ophthalmologists office.

Secondary outcome

Secondary endpoints are the registration of adherence by the Travalert, the weight of the medication bottles, patient satisfaction and refill compliance in the next three years.

Study description

Background summary

Non-adherence with prescribed topical therapy is a frequently encountered problem in glaucoma patients of which the impact on intraocular pressure levels and visual field loss is not yet known.
Non-adherence may possibly be improved with the use of electronic monitoring devices and/or drop aids. The Travalert* dosing aid is a recently developed monitoring device for the use of travoprost (Travatan*) or the fixed combination timolol-travoprost (Duotrav*) eye drops. The use of a drop guider (Travalert*-Eyot*), fastened onto the Travalert, may be of additional value for the correct instillation of drops into the eye. Patient education may also be useful to achieve better adherence with medication.

Study objective

To study the effect on intraocular pressure in patients using the Travalert dosing aid with or without the additional use of the Eyot and with of without additional patient education.

Study design

randomized clinical trial with a 2x2 factorial design.

Intervention

1. Use of the Travalert dosing aid
2. Use of the Travalert with the Eyot drop guider
3. Use of the Travalert together with patient education
4. Use of the Travalert and Eyot together with patient education

Study burden and risks

Glaucoma patients are requested to fill in several questionnaires. Furthermore, they are asked to use the Travalert and 50% will also be using the Eyot which may be very helpful for them. Fifty percent of patiens will receive patient education by an assistant, which may also be beneficial for them. Follow-up visits to the outpatient clinic will be scheduled at 3 and 6 months after inclusion in the study. These visits closely reflect common practice in the management of glaucoma. There are no risks involved for participating patients.

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

Diagnosis glaucoma or ocular hypertension
Treatment with travoprost or travoprost/timolol

Exclusion criteria

High risk of side effects expected from travoprost or travoprost/timolol
Absolute inability to administer eye drops
Difficulty in reading or speaking Dutch

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2007
Enrollment:	1000
Type:	Actual

Medical products/devices used

Generic name:	Travalert dosing aid
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-05-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-08-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-01-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-02-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-03-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-11-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL16962.068.07