The Ocular Coil Drug delivery Comfort (OCDC) trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders
Study type	Observational non invasive

Summary

ID

NL-OMON47468

Source
ToetsingOnline

Brief title
OCDC

Condition

- Eye disorders

Synonym
niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Oogheelkunde
Source(s) of monetary or material Support: Chemelot InScite (Instute for Science and Technology),DSM

Intervention

Keyword: drug delivery, ocular coil, ophthalmology

Outcome measures

Primary outcome

The primary objective is the evaluation of the safety of the ocular coil.

Secondary outcome

Secondary objectives are coil retention (duration), subject comfort (tolerance)

and incidence of adverse effects and complications.

Study description

Background summary

Current ocular drug delivery systems, such as eye drops and ointments, suffer from low bioavailability of the drug, a very short duration of action, initial high drug concentrations, considerable systemic absorption of the drug and difficulty to instil eye drops or ointments. In addition, patient compliance (the degree to which a patient correctly adheres to the directions for use of a medical advice) is low with eye drops and ointments due to high frequency of administration. Due to these shortcomings, ocular diseases are not being treated adequately and may further progress and lead to blindness.

Study objective

The new drug delivery device is a rod-shaped metal bar, called an ocular coil. The coil can be loaded with one (or more) drug(s) en can be placed easily in the lower eyelid of the eye. In this way, the drug can be released to the eye in a constant and sustained way.

Study design

In this phase of the research, the coil will not be loaded with drugs. The coil will be placed in the lower eyelid of one eye. Afterwards, the comfort and safety of the coil will be evaluated. The contralateral eye will serve as control eye. Before and after insertion of the coil, both eyes will be investigated by several ophthalmologic examinations. In addition, the volunteers will be asked to complete questionnaires related to the comfort of

the coil in the eye.
The coil will be inserted in the eye for 4 weeks (day and night). During this period, the eyes will be frequently examined (30 min per check-up). The volunteers will receive a follow-up scheme for each check-up. The check-ups will be performed at 30 min, 8 hours, 24, 48 hours and 1, 2, 3, 4 week after insertion of the coil (total = 9 check-ups). The volunteers are expected to be present at each check-up. We expect that wearing the coil will not influence the daily life of the volunteers.

Study burden and risks

This following risks are associated with participation of the study:
* Irritation of the eye
* Infection of the eye

Contacts

Public
Selecteer

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Scientific
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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 between 18 and 75 years old
* Informed and having given informed consent
* Willing and able to comply with scheduled visits and other study procedures
* If wearing contact lenses, willing to replace them for glasses for the duration of the study

Exclusion criteria

* Subjects with a history of eye disease
* Subjects using eye drops (during the study).
* Subjects with an Oriental/Asian lid crease, because of their narrow fornix.
* Subjects who do not speak and/or write Dutch properly.
* Subjects with a history of serious adverse reaction or hypersensitivity
- Subjects with hay fever
* Women who are pregnant or nursing their child, or have the intention to become pregnant during the course of the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2018
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Ocular coil
Registration:	No

Ethics review

Approved WMO Date:	20-07-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-03-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-06-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-02-2019
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
ClinicalTrials.gov	NCT03488017
CCMO	NL57050.068.16