Trabeculectomy with Ologen®-Pilot

Published: 20-02-2013
Last updated: 25-04-2024

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

Summary

ID

NL-OMON40101

Source
ToetsingOnline

Brief title
Trabeculectomy-Ologen® (Pilot)

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma, primary open-angle glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Aeon Astron Europe B.V.

Intervention

Keyword: Glaucoma surgery, Ologen®, Trabeculectomy

Outcome measures

Primary outcome

Main study parameter/endpoint

• The number of patients with an intraocular pressure level of 15 and lower, and at least a 20% decrease from baseline at the last postoperative visit (three months after surgery).

Secondary outcome

Secondary study parameters/endpoints

• The number of glaucoma medications needed at the last postoperative visit.

• Peroperative and postoperative complications after trabeculectomy with adjuvant Ologen® implantation.

• Postoperative bleb aspect after trabeculectomy with adjuvant Ologen® implantation.

• Surgery time of trabeculectomy with adjuvant Ologen® implantation.

• Complexity of the surgical procedure (trabeculectomy with adjuvant Ologen® implantation); number of sutures, handling (resizing and reshaping) the Ologen® implant.

• The number of patients withdrawn from the study as a result of failure of the surgical procedure and needing additional eye surgery.

Study description

Background summary

Trabeculectomy has been the gold standard procedure for the surgical treatment of patients with glaucoma for several decades. To prevent scarring of the

filtering bleb, nowadays antimetabolites such as mitomycin-C are widely used as an adjunctive during surgery. However, trabeculectomy with mitomycin-C in general has been reserved for experienced glaucoma surgeons due to the possible hazards of antimetabolites.
Recently, a new biodegradable porous collagen-glycosaminoglycan (CAG) copolymer matrix implant (Ologen® collagen matrix (Aeon Astron Europe BV, Leiden, The Netherlands) has been developed for glaucoma surgery. When placed over the scleral flap, its porous structure should force conjunctival fibroblasts and myofibroblasts to grow into the pores and secrete connective tissue in the form of a loose matrix, reducing scar formation and wound contraction. The device should completely degrade within 90-180 days after implantation.
Ologen® implantation may probably be a safe alternative for trabeculectomy with mitomycin-C. Additionally, it may be cost-effective due to both a reduction in primary surgery time as post-operative follow-up visits. Furthermore, an easier operating technique could make glaucoma surgery more interesting for less experienced surgeons. And lastly, less early and late onset bleb related complications due to the use of antimetabolites can be expected.

Study objective

The primary objective is the degree of IOP lowering after trabeculectomy with adjuvant Ologen® implantation, in comparison to trabeculectomy with mitomycin-C. Secondary objectives are peroperative and postoperative complications, and postoperative bleb aspect after trabeculectomy with adjuvant Ologen® implantation, in comparison to trabeculectomy with mitomycin-C.

Study design

Prospective intervention pilot study (with an external (historical) control group), in which glaucoma patients who are scheduled for trabeculectomy with mitomycine-C will be asked their consent for using an Ologen® implant instead of applicating mitomycin-C as an adjuvant.

Intervention

The intervention is trabeculectomy with implantation of an Ologen® implant as a primary surgical procedure for patients with primary open-angle glaucoma. The results will be compared with retrospective results of routine trabeculectomy with mitomycin-C.

Study burden and risks

There are no extra risks to be expected. In contrast, mitomycin-C has the risk for creating thin bleb walls, avascular blebs, and increased risk to infection, blebitis and endophthalmitis. For Ologen® there is probably less risk to infection, blebitis and endophthalmitis. Additionally, success rates may be

comparable, with no prior preparation required (compared to mitomycin-C), and operation time may be saved.

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 18 year or older.
• Primary open-angle glaucoma with progression of visual field loss and/or uncontrolled intraocular pressure levels with medication.
• Indication for trabeculectomy with mitomycin-C.

Exclusion criteria

• Unability to discontinue oral anticoagulants.
• Previous ocular surgery (with the exemption of clear cornea cataract surgery).
• Ocular infection within 14 days prior to trabeculectomy.
• Pregnant and breastfeeding women.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Ologen biodegradable matrix
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-02-2013
Application type:	First submission

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	NCT01753492
CCMO	NL42312.068.12