Macular Edema following cataract surgery in Diabetic type 2 patients

Published: 10-09-2009
Last updated: 04-05-2024

To identify the relative risk of ME following cataract surgery in patients with DM type 2 and mild to moderate non-proliferative diabetic retinopathy, compared to diabetics type 2 not undergoing cataract surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Interventional

Summary

ID

NL-OMON33232

Source
ToetsingOnline

Brief title
DME & Cataract

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetic macular edema

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cataract surgery, diabetes type 2, macular edema

Outcome measures

Primary outcome

Incidence DME, BCVA, foveal thickness.

Secondary outcome

IOP.

Study description

Background summary

Diabetic Macular Edema (DME) is a frequent complication in patients with diabetes mellitus (DM), especially in late onset (type 2) diabetes. Moreover, it is frequently observed that DME occurs, recurs or progresses after cataract surgery. As cataract surgery is the most frequently performed surgical intervention (20% of over 65 pt and 50% of over 75 pt) and a substantial part of the elderly population in developed countries develops diabetes mellitus type 2 (over 1 in 6 persons over 65 year), a significant group of patients undergoing cataract surgery is at risk for developing DME.
Although several interventional studies have been conducted to prevent postoperative macular edema in DM type 2 patients, they are characterised by their relative small numbers and disregarding the diabetic retinopathy (DRP) stage. Moreover, it is not exactly known what the risk of DME is after cataract surgery. Therefore, this study evaluates the relative risk of developing macular edema in diabetic patients with mild to moderate non proliferative diabetic retinopathy (NPDRP) after cataract extraction, compared to diabetics not undergoing surgery. Furthermore, this study may serve as a baseline for future studies evaluating medical intervention to reduce postoperative macular edema in diabetics.

Study objective

To identify the relative risk of ME following cataract surgery in patients with DM type 2 and mild to moderate non-proliferative diabetic retinopathy, compared to diabetics type 2 not undergoing cataract surgery.

Study design

Prospective, open-label, randomized.

Intervention

Group 1: No intervention; Group 2: Phaco-emulsification, Dexamethason collyre 3/d.

Study burden and risks

For patients of group 1, cataract surgery will be suspended. The prolongation of hampered vision may be experienced as inconvenient; the risk of developing DME will be reduced during that period. For patients of group 2 the situation is reversed.

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Informed consent
- Cataract
- Diabetes Mellitus type 2
- Mild to moderate non-proliferative diabetic retinopathy

Exclusion criteria

- Severity of cataract obstructing ophthalmic inspection (i.e. NO5, NC5, NO6, NC6, C5, P5) and/or (sufficiently accurate) OCT measurements (i.e. a Signal Strength Index < 35).
- Any other corneal, media, retinal or optic nerve disorder, except stage I dry ARMD
- Clinically significant macular edema
- Pregnant, no active birth control
- Use of Diamox
- Use of Avandia (rosiglitazone)
- Use of oral steroids
- Use of Coumarin derivatives and heparin derivatives
- Status after ablatio retina/vitrectomy
- History of steroid response

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	02-02-2010
Enrollment:	170
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	10-09-2009
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	NL28882.078.09