Macular Edema following cataract surgery
in Diabetic type 2 patients.

Gepubliceerd: 24-09-2009 Laatst bijgewerkt: 18-08-2022

The relative risk of developing macular edema in diabetics after cataract surgery is enhanced.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23857

Bron
Nationaal Trial Register

Verkorte titel
DME & cataract

Aandoening

Diabetes Mellitus type 2
Cataract

Ondersteuning

Primaire sponsor: The Rotterdam Eye Hospital
PO Box 70030
3000 LM Rotterdam
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Overige ondersteuning: Stichting Wetenschappelijk Onderzoek Oogziekenhuis – Prof. Dr. Flieringa (SWOO)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Incidence of DME. DME is defined as an increase in mean foveal thickness on OCT of 30% or more from preoperative baseline. No distinction will be made between Irvine-Gass syndrome or evolving diabetic maculopathy, as it is impossible to differentiate these entities and, moreover, this is clinically not relevant. As such, presence or absence of retinal microauneurysms, retinal exudates or cystoid pattern on OCT will not be taken into account to diagnose DME;

2. Best Corrected Visual Acuity (ETDRS) at baseline, day 1, week 4, 12, 24 and 52;

3. Mean Foveal Thickness (OCT) at baseline, day 1, week 4, 12, 24 and 52.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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.

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.

Study population:

Patients with DM type 2 and mild to moderate NPDRP.

Intervention:

Group 1: No intervention;

Group 2: Phaco-emulsification, Dexamethasone 3/d.

Main study parameters:

BCVA, foveal thickness.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Doel van het onderzoek

The relative risk of developing macular edema in diabetics after cataract surgery is enhanced.

Onderzoeksopzet

Baseline, day 1, week 4, 12, 24 and 52.

Onderzoeksproduct en/of interventie

Phaco-emulsification.

One group will receive phaco=emulsification (cataractoperation), while the other group will not receive the operation (within one year).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Informed consent;

2. Cataract (LOCS-III grading to document severity);

3. Diabetes Mellitus type 2, which is defined as chronic disease leading to high blood glucose levels due to defects either in insulin secretion or in insulin action in the body. Type 2 diabetes refers to an onset past the age of 30 years, regardless of the dependence on insulin;

4. Mild to moderate non-proliferative diabetic retinopathy, as defined by the International Clinical Diabetic Retinopathy Disease Severity Scale:

·Mild NPDRP: microaneurysms only
·Moderate NPDRP: more than just microaneurysms but less than severe NPRDP which includes any of the following: more than 20 intraretinal hemorrhages in each of four quadrants, definite venous beading in 2 or more quadrants, prominent IRMA on 1 or more quadrants;

5. Statines are permitted;

6. Antihypertensive drugs are permitted;

7. All anti-DM drugs are permitted, except Avandia (and derivatives);

8. All anti-aggregantia are permitted.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. 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);

2. Any other corneal, media, retinal or optic nerve disorder, except stage I (AREDS) dry ARMD;

3. Clinically significant macular edema (CSME), as defined by the ETDRS as follows:

a. Thickening of the retina at or within 500 microns of the center of the macula.

b. Hard exudates at or within 500 microns of the center of the macula, if associated with thickening of the adjacent retina (not residual hard exudates remaining after the disappearance of retinal thickening).

c. A zone or zones of retinal thickening one disc area or larger, any part of which is within one disc diameter of the center of the macula.

4. Pregnant, no active birth control;

5. Use of Diamox;

6. Use of Avandia (rosiglitazone);

7. Use of oral steroids;

8. Use of Coumarin derivatives and heparin derivatives;

9. Status after ablatio retina/vitrectomy;

10. History of steroid response.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	11-01-2009
Aantal proefpersonen:	170
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-09-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1907
NTR-old	NTR2024
Ander register	Oogziekenhuis Rotterdam / MEC ErasmusMC / ABR nummer (CCMO) : 2009-11 / 2009-263 / NL28882.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A