Treatment of Cystoid Macular Edema following cataract surgery. A randomized, double-masked, placebo-controlled, clinical trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26441

Source
Nationaal Trial Register

Health condition

Cystoid Macular Edema (CME) after phacoemulsification.

Sponsors and support

Primary sponsor: Het Oogziekenhuis Rotterdam
Postbus 70030
3000 LM Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Het Oogziekenhuis

Intervention

Outcome measures

Primary outcome

At 12 weeks:

1. Optical Coherence Tomography (OCT)-proven CME (yes/no);

2. Best corrected visual acuity as determined by ETDRS.

Secondary outcome

1. OCT-proven CME (yes/no);

2. Clinical CME (yes/no) (i.e CME with reduced visual acuity of 2 or more lines);

3. Best corrected visual acuity as determined by ETDRS;

4. Thickness of the macula, examined by OCT RTVue (Optovue);

5. Active inflammation as measured by Laser flare count

Study description

Background summary

Rationale:

Cataract extraction is the most frequently performed surgical intervention. One of the most common causes of poor visual acuity after cataract surgery is the development of postoperative clinical (cystoid) macular edema ((C)ME). Several treatment options have been investigated, but a uniform treatment protocol does not exist.
The current treatment strategies range from no to very intensive treatment with no strategy showing unambiguous benefits. However, based on our experience and extensive literature review, it is likely that a treatment using local application of a corticosteroid and a non-steroidal anti-inflammatory drug will be optimal. Therefore, the efficacy of treatment of CME with a combination of these types of drug will be investigated.

Objective:

To study the efficacy of treatment with Nevanac in combination with Pred Forte of Cystoid Macular Edema after phacoemulsification.

Study design:

Prospective randomized double-masked placebo-controlled clinical trial.

Study population:

Patients diagnosed with clinical CME within three months after phacoemulsification.

Intervention:

Group 1: Placebo eyedrops in two separate phials.

Group 2: 6 weeks treatment of nepafenac 0,1% eye drops 3 d.d., plus prednisolone acetate 1% eye drops 3 d.d.

Main study parameters/endpoints:

Before treatment and 4, 8, 12, 20 and 52 weeks after treatment has started:

1. Prevalence of (C)ME;

2. Best Corrected Visual Acuity by ETDRS;

3. Inflammation parameter (Laser flare count) by Laser Flare Meter;

4. Thickness of the macula, by OCT.

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

There are no risks involved for patients in group 1; possible side effects of medication used in this study (group 2) can be found in the respective SPC's. Six study-related visits are scheduled, which will take 30 minutes each. Measurements are not invasive; burden is low.

Study objective

Treatment with Nevanac in combination with Pred Forte of Cystoid Macular Edema after phacoemulsification is superior to placebo.

Study design

4, 8,12, 20, 52 weeks.

Intervention

1. Group 1: Placebo eyedrops in two separate phials;

2. Group 2: 6 weeks treatment of nepafenac 0,1% eye drops 3 times a day (d.d.), plus prednisolone acetate 1% eye drops 3 d.d.

Contacts

Public
Oogziekenhuis Rotterdam
Schiedamsevest 180
P.W.T. Waard, de
Rotterdam 3011 BH
The Netherlands
+31(0)10 4017777
Scientific
Oogziekenhuis Rotterdam
Schiedamsevest 180
P.W.T. Waard, de
Rotterdam 3011 BH
The Netherlands
+31(0)10 4017777

Eligibility criteria

Inclusion criteria

1. Diagnosed or suspect clinical CME within three months after phacoemulsification;

2. CME on OCT;

3. Age > 18 years;

4. Informed consent;

5. Patients must be able to comply with the study protocol.

Exclusion criteria

1. Diabetes mellitus I/II;

2. Corneal complications;

3. Age related macula degeneration (wet and dry);

4. History of retinal detachment;

5. History of vitrectomy;

6. Macular disease;

7. History of steroid response (IOP-rise);

8. Hypersensitivity to NSAIDs / NSAID-induced asthma;

9. Use of systemic steroid medication / NSAIDs;

10. Pregnancy;

11. M. Addison / adrenal gland failure;

12. Chronic angle-closure glaucoma;

13. Complicated cataract operation;

14. Keratoconjunctivitis sicca;

15. Rheumatoid arthritis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-05-2010
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion Date:	12-04-2010
Application type:	First submission

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
NTR-new	NL2156
NTR-old	NTR2280
Other	MEC-2010-008 : OZR-2009-06
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
NA