Triamcinolone and Macula Grid Laser for Diffuse Diabetic Macular Edema

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To show in a prospective randomised study if intravitreal injection of Triamcinolonacetonide combined with Macula Grid Laser gives a better increase in visual acuity and/or decrease in macular edema than Macula Grid Laser combined with sub-Tenon...

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

Summary

ID

NL-OMON29703

Source
ToetsingOnline

Brief title
Triamcinolone and Macula Grid Laser for Diffuse Diabetic Macular Edema

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
diabetic retinal edema, exsudative diabetic retinopathy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetes, Laser, Macula, Triamcinolone

Outcome measures

Primary outcome

Change in mean ETDRS visual acuity 6 months after Macula Grid Laser and change in macular thickness measured by OCT compared to the situation before treatment.

Secondary outcome

Change in visual acuity. Subjective change in visual acuity. Laserenergy needed for minimal visible effect. Incidence of side effects as rise in intraocular pressure, cataract formation, endophthalmitis, retinal detachment. Amount of leakage on fluorescein angiography.

Study description

Background summary

Diabetic Macular Edema is the most frequent cause of visual impairment in patients with Diabetic Retinopathy.
Our study will compare the effect of two therapies for Diffuse Diabetic Macular Edema.
Diffuse Diabetic Macular Edema can be treated in different ways. Macula Grid Laser photocoagulation (MGL) is a well-known treatment to stabilise the visual acuity.
Intravitreal Triamcinolonacetonide is another treatment for Diffuse Diabetic Macular Edema and causes a strong decrease in macular edema and increase in visual acuity, but has a limitid effect from 2 to 6 months.
At the moment Diffuse Diabetic Macular Edema is also treated by a combination of laser treatment and Triamcinolonacetonide.
After a decrease in macular edema caused by the Triamcinolonacetonide, the effect from the laser can be achieved with less laser energy. Except for an increase in visual acuity, this is also a way to limit scotomas caused by the laser treatment and to decrease the need for retreatments with

Triamcinolonacetonide.
Instead of intravitreal administration, Triamcinolonacetonide can also be injected sub-Tenon. This form of administration has less side-effects, but the intraoculair availability is less than with the direct intravitreal injection.
At present laser treatment is performed in combination with either sub-Tenon or intravitreal administration of Triamcinolonacetonide, but there is no study that compares the results of these two methods.

Study objective

To show in a prospective randomised study if intravitreal injection of Triamcinolonacetonide combined with Macula Grid Laser gives a better increase in visual acuity and/or decrease in macular edema than Macula Grid Laser combined with sub-Tenon Triamcinolonacetonide injection.

Study design

Prospective randomized interventional study with two groups.

Intervention

Group 1: Posterior sub-Tenon injection of Triamcinolonacetonide (20 mg in 0,5 ml) followed after 1 month by Macula Grid Laser (Argon Green laser).
Group 2: Intravitreal injection of Triamcinolonacetonide (10 mg in 0.1 ml) followed after 1 month by Macula Grid Laser (Argon Green laser).

Study burden and risks

The burden and risks for the patient are equal to the treatment outside this study, except for one extra venous tap (8ml). Total amount of time needed for treatment and follow up will be around 8 hours in group 1 and 10 hours in group 2. Burden and risks for group 2 are higher than for group 1 because of the intravitreal administration of the Triamcinolonacetonide in group 2.

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 jaar
Diabetes Mellitus I or II
Clinically Significant macular Edema (< 1 year; mainly diffuse leakage on fluorescein angiogram)
Best corrected visual acuity 0.1 tot 0.4
HbA1C < 10.0
Blood pressure < 160/100 mm Hg
Intraocular pressure < 21 mm Hg

Exclusion criteria

Mainly focal leakage from microaneurysms
Mainly cystoid leakage
Proliferative Diabetic Retinopathy
Previous Macula Gridlaser
Panretinal photocoagulation < 6 months before inclusion
Preretinal or vitreous hemorrhage
Tractional retinal detachment
Significant media opacities obscuring evaluation and treatment of macula
Iris neovascularisations
Preëxistent amblyopia with VA < 0.2
Previous vitreoretinal surgery
Cataractsurgery < 6 months before inclusion

Intraocular pressure > 22 mm Hg
Glaucoma and/or steroïdresponder
Age related macula degeneration, uveïtis
Vitreomacular traction and/or macula pucker (fundoscopically and/or OCT)
Macula ischaemia (enlargement or irregular foveal avascular zone and/or 6 clock hours of macular capillary nonperfusion on fluorescein angiography)
Other ocular disease where intraocular surgery is needed.
Chronic renal failure with need for dialysis or renal transplant
Allergy for Triamcinolonacetonide

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Kenacort-A
Generic name:	Triamcinolonacetonide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2006-000884-27-NL
CCMO	NL12046.091.06