Navilas™ laser versus classic frequency doubled Nd-YAG (532 nm) laser therapy for diabetic macular edema. A randomized study analyzing the effect on central visual function.

No registrations found.

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

Summary

ID

NL-OMON22871

Source
Nationaal Trial Register

Brief title
NAVILAS

Health condition

Diabetic macular edema.

Sponsors and support

Primary sponsor: The Rotterdam Eye Hospital /
Het Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Outcome measures

Primary outcome

Change of microperimetry outcome (dB) at 6 months.

Secondary outcome

1. Change of microperimetry outcome (dB) at 3, 9 and 12 months;

2. Change of BCVA (ETDRS), CFT (OCT), autofluorescence (objective macular damage) at 3, 6, 9, 12 months;

3. Change of total area of laser burns or retinal pigment epithelium atrophy over time.

Study description

Background summary

Rationale:

Diabetic macular edema (DME), the incidence of which is expected to increase to 12,500 new patients annually in the Netherlands in 2025, often results in severe visual acuity loss. Visual loss can be significantly reduced by grid laser photocoagulation. With an image-guided retina laser (Navilas™) it is possible to accurately execute the intended treatment without causing unnecessary retinal damage. Thus visual loss may be further prevented.

Objective:

To study the impact of laser photocoagulation on the parafoveal visual field in a previously untreated population of patients with DME.

Study design:

Prospective, randomized, double-masked, 3-arms, comparative study.

Study population:

Patients with recently diagnosed DME without prior treatment.

Intervention:

Arm 1: Standard laser photocoagulation treatment;

Arm 2: Navilas™ threshold preset laser pattern;

Arm 3: Navilas™ subthreshold preset laser pattern.

Main study parameters/endpoints:

Change of microperimetry outcome (dB) at 6 months.

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

Treatment in all groups is expected to be equally effective with respect to visual acuity and central foveal thickness. Group 3 may benefit from subthreshold laser because less damage is caused. Burden is considered to be moderate to low. All study related measurements will take place during regular control visits. Microperimetry requires the subject's concentrated attention for about half an hour and may be somewhat tiresome. Extra study-related time amounts to approximately 5 hours (1 hour per visit).

Study objective

With an image-guided retina laser (Navilas™) it is possible to accurately execute the intended treatment without causing unnecessary retinal damage while further visual loss is prevented.

Study design

3, 6, 9, 12 months.

Intervention

Arm 1: Standard laser photocoagulation treatment;

Arm 2: Navilas™ threshold preset laser pattern;

Arm 3: Navilas™ subthreshold preset laser pattern.

Contacts

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Eligibility criteria

Inclusion criteria

1. Informed consent;

2. Age 30 years or older;

3. Recently diagnosed DME (< 3 months);

4. Diabetes mellitus (i.e. at least 1 year of treatment, and a HbA1c < 10 %);

5. Able to cooperate with assessments of visual acuity, retinal imaging and microperimetry.

Exclusion criteria

1. Other ocular condition affecting macular function or obscuring ocular media, thereby influencing visual acuity and/or central visual sensitivity;

2. Previous panretinal laser;

3. Intraocular injections or surgery (< 3 months prior to inclusion);

4. Planned laser (PRP), intravitreal injections or surgery (phaco/vitrectomy) within 12 months after inclusion;

5. Fluorescein allergy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2011
Enrollment:	99
Type:	Actual

Ethics review

Positive opinion

Date:	09-12-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35722
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3040
NTR-old	NTR3188
CCMO	NL37528.078.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35722

Study results

Summary results
N/A