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.

Published: 29-11-2011
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To study the impact of laser photocoagulation on the parafoveal visual field in a previously untreated population of patients with DME.

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

Summary

ID

NL-OMON35722

Source
ToetsingOnline

Brief title
NAVILAS

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders
- Diabetic complications

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: diabetic macular edema, laser photocoagulation, parafoveal visual field

Outcome measures

Primary outcome

Change of microperimetry outcome (dB) at 6 months.

Secondary outcome

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

Change of BCVA (ETDRS), CFT (OCT), autofluorescence (objective macular damage)

at 3, 6, 9, 12 months.

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

time.

Study description

Background summary

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.

Study 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.

Intervention

Arm 1: Standard laser photocoagulation treatment.
Arm 2: Navilas* threshold preset laser pattern.
Arm 3: Navilas* subthreshold preset laser pattern.

Study burden and risks

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).

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
NL
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Informed consent.
Age 30 years or older.
Recently diagnosed DME (< 3 months).
Diabetes mellitus (i.e. at least 1 year of treatment, and a HbA1c < 10 %).
Able to cooperate with assessments of visual acuity, retinal imaging and microperimetry.

Exclusion criteria

Other ocular condition affecting macular function or obscuring ocular media, thereby influencing visual acuity and/or central visual sensitivity.
Previous panretinal laser.
Intraocular injections or surgery (< 3 months prior to inclusion).
Planned laser, intravitreal injections or surgery (phaco/vitrectomy) within 12 months after inclusion.
Fluorescein allergy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2012
Enrollment:	99
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2011
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

ID: 22871
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37528.078.11
OMON	NL-OMON22871