Long-term follow-up and cross-over of treatment with high-density micropulse laser and half-dose photodynamic therapy in participants of the PLACE trial for chronic central serous chorioretinopathy.

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Primary objectives:- To investigate the long-term outcome after successful treatment (no subretinal fluid on OCT) in the PLACE trial.- To investigate whether a cross-over treatment of half-dose PDT to HSML in cCSC patients who either did not respond...

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

Summary

ID

NL-OMON40728

Source
ToetsingOnline

Brief title
CROSS-OVER/LONG-TERM FOLLOW-UP STUDY for chronic CSC, following PLACE trial

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
Chronic central serous chorioretinopathy

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: fondsen

Intervention

Keyword: chronic central serous chorioretinopathy, Half-dose photodynamic therapy, micropulse laser therapy

Outcome measures

Primary outcome

- Absence of subretinal fluid on OCT at the long-term follow up visit, one year

after baseline (final visit of the PLACE trial).

- Absence of subretinal fluid on OCT at the evaluation visit 6-8 weeks after

either first or second cross-over treatment as compared to either baseline

(baseline = visit (last evaluation) at 7-8 months after first treatment in

PLACE trial) or first re-treatment evaluation visit.

Secondary outcome

- Mean change in ETDRS BCVA in the study eye from baseline to final follow-up

visit (1 year after baseline).

- Mean change in retinal sensitivity on microperimetry in the study eye from

baseline to final follow-up visit (1 year after baseline).

- Mean change in the NEI VFQ-25 questionnaire from baseline to final follow-up

visit (1 year after baseline).

- Number of recurrences of CSC within follow-up period.

Study description

Background summary

Chronic central serous chorioretinopathy (CSC) is a relatively frequent eye disease that often occurs in patients in the professionally active age range. In this disease, there is pooling of fluid under the central retina (the macula). This specific form of macular degeneration can cause permanent vision loss, image distortion, loss of color and contrast vision due to this fluid under the retina. An early diagnosis and treatment may improve the visual outcome and quality of life. To date there is no international consensus on the optimal treatment of chronic CSC. Many retrospective studies suggest that treatment with photodynamic therapy (PDT) is effective in chronic CSC. Micropulse laser (ML) therapy may
also be effective in this disease.
This study follows the PLACE trial, which was the first prospective randomized controlled trial in chronic CSC. In this trial the long-term effect of treatment with either PDT or ML will be investigated. Also, a possible additional effect of applying a cross-over treatment (PDT in patients who received ML during the PLACE trial, and vice versa) will be studied.

Study objective

Primary objectives:
- To investigate the long-term outcome after successful treatment (no subretinal fluid on OCT) in the PLACE trial.
- To investigate whether a cross-over treatment of half-dose PDT to HSML in cCSC patients who either did not respond or who showed recurrence of subretinal fluid in the PLACE trial, and vice versa, results in an absence of subretinal fluid on OCT.

Secondary objective:
To investigate the clinical outcome comparing half-dose PDT treatment with HSML treatment in patients with cCSC subretinal fluid due to active leakage in chronic CSC, based on evaluation of best-corrected visual acuity, retinal sensitivity on microperimetry, and subjective success score on the NEI VFQ-25 questionnaire of visual functioning.

Study design

Prospective open-label follow-up and cross-over trial.

Intervention

Patients who will be included in the cross-over study, will receive an

intervention. If a patient received half-dose photodynamic therapy during the PLACE trial, high-density subthreshold micropulse laser therapy will be executed. If a patient received high-density subthreshold micropulse laser therapy during the PLACE trial, half-dose photodynamic therapy will be executed.

Half-dose PDT treatment
For this intervention the patients need dilated pupils (with 1.0% tropicamide and 2,5% phenylephrine). All patients will get an intravenous drip through which 3 mg/m2 verteporfin (Visudyne ®) (half-dose) is administered, with an infusion time of 10 minutes. At exactly 15 minutes after the start of the infusion, an anesthetic eye drop is given (oxybuprocaïne 0.4% or equivalent), a contact glass (a Volk® PDT lens, magnification of 1.5x) is positioned on the affected eye, and the aiming beam of the laser is focused on the treatment area. The magnification factor is taken into account in the settings of the PDT machine. The area of treatment is chosen, with the area of the aiming beam corresponding to the area of the
subsequent laser spot area. The area that has to be treated is determined based on those hyperfluorescent area(s) on mid-phase (approximately 10 minutes) ICG-angiography that correspond to subretinal fluid accumulation in the macula on the OCT scan and hyperfluorescent *hot spots* on the mid-phase (approximately 3 minutes) fluorescein angiogram. The spot size will be defined based on diameter of the hyperfluorescent area on ICG angiography plus 1mm. The treatment is performed with standard 50 J/cm2 fluency, a PDT laser wavelength of 689 nm, and a standard treatment duration of 83 seconds. Care must be taken to treat at exactly 15 minutes after the start of the infusion, to maximize the localization of the effect of treatment to the choroid and minimize possible damage to the adjacent retinal structures. The PDT treatment must take place at least 45 minutes after ICG angiography has been performed.

High-density subthreshold micropulse laser (HSML) treatment
For this intervention the patients need dilated pupils (with 1.0% tropicamide and 2,5% phenylephrine). An anaesthetic eye drop is given (oxybuprocaïne 0.4% or equivalent), and a contact glass (for instance a Volk® Area Centralis lens) is positioned on the affected eye. HSML treatment with an 810 nm diode laser (Iridex, Mountain View, United States) will be performed of the areas identified on mid-phase ICG angiography. Multiple confluent, adjacent (non-overlapping) laser spots will be applied, covering the leakage area on mid-phase ICG angiography. The number of spots and number of zones treated depend on the extent of the leakage area(s) on mid-phase ICG. The area that has to be treated is determined based on those hyperfluorescent area(s) on mid-phase (approximately 10 minutes) ICG-angiography that
correspond to subretinal fluid accumulation in the macula on the OCT scan and hyperfluorescent *hot spots* on the midphase (3 minutes) fluorescein angiogram. The following HSML treatment settings will be used: a power of 1800 mW*, a duty cycle of 15%, frequency of 500 Hz, exposure time of 0.2 s per spot, spot size: 125 µm, minimal distance of spot from fovea: 500 µm.

* Subthreshold treatment is desired, meaning that no visible reaction due to laser treatment has to be seen in the retina. In virtually all patients, a power of 1800 mW wil not produce a visible discoloration of the retina after application of a laser spot with the aforementioned settings. If retinal discoloration is seen at a power of 1800 mW (corresponding to suprathreshold treatment), for instance in patients with darkly pigmented fundi, the power will be reduced with steps of 300 mW until there is no visible reaction. The first laser *test* spot will always be applied juist outside the macular area.

Study burden and risks

It is possible that by exception extra visits may be necessary in addition to standard clinical care, because in some cases not all examinations may be possible on the same day. This may for instance be the case if an extra visit is necessary to complete the clinical examinations that are required to judge eligibility.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Only participants of the PLACE trial can be enrolled for this study.
In the Cross-over study, the following patients will be included:
- Subjects with persistent SRF on OCT at the final follow-up visit of the PLACE trial (7-8 months after Treatment Visit 1 PLACE trial) after either two PDT treatments in or two HSML treatments,
- Subjects with recurrence of SRF on OCT at the final follow-up visit of the PLACE trial after one PDT or one HSML treatment, will be included in the cross-over study.
Of note, for SRF on OCT does not have to involve the fovea for patients to be included in the cross-over study.
In the Long-term follow-up study, the following patients will be included:
- Subjects who do not show any SRF on OCT at final visit of the PLACE trial will be included.
Of note, patients who were not initially included in the long-term follow-up study, because of persistent SRF on OCT, were automatically included in the cross-over study.

Exclusion criteria

For this study no exclusion criteria are applicable.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	31-03-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-04-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-08-2015
Application type:	Amendment
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
CCMO	NL50642.091.14

Study results

Date completed:	30-05-2018
Actual enrolment:	92

Summary results
Trial is onging in other countries