Early treatment of central serous retinopathy by photodynamic therapy. A randomized controlled trial.

No registrations found.

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

Summary

ID

NL-OMON20530

Source
NTR

Brief title
CSR & PDT

Health condition

Central serous retinopathy.

Sponsors and support

Primary sponsor: Het Oogziekenhuis Rotterdam
Schiedamse Vest 180
3011 BH Rotterdam
Nederland
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Outcome measures

Primary outcome

Visual acuity at 1 year (ETDRS letter cart).

Secondary outcome

1. Metamorphopsia (Amsier cart);

2. Color vision (Hardy Rand Ritter colortest);

3. Recurrence (Optical Coherence Tomographt);

4. Presence of persistent subretinal fluid on OCT;

5. Lesion size on autofluorescence imaging (OCT).

Study description

Background summary

Rationale:

There is no agreement concerning the early treatment of central serous retinopathy (CSR). In literature, clinical case series using photodynamic therapy (PDT) show favorable results.
No randomized controlled trials however exist. In the last trial 'Long term follow-up of central serous retinopathy. An observational case series' (protocol OZR-2007-02, MEC-2007-105) prognostic factors available at first presentation could be identified. As a result of these findings,
this protocol proposes a randomized controlled trial in patients with CSR with poor prognostic factors. Patients will be randomized between an observational and an early PDT treatment arm. In
the observational arm, patients with persistent lesions at 3 months will be treated with PDT in agreement with current standard of care.

Objective:

To determine the outcome in CSR patients comparing treatment with PDT versus observation.

Study design:
Prospective randomized controlled trial.

Study population:
Patients presenting with CSR (N=50) with poor prognostic factors.

Main study endpoint:
Visual acuity at 1 year.

Secondary study endpoints: Metamorphopsia, color vision, recurrence, presence of persistent subretinal fluid on OCT, lesion size on autofluorescence imaging.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Risks are considered to be small.

Study-related visits and/or time:

Extra visits (3 &4) at 3 & 6 months; extra time 4X30 minutes (visits 1, 3, 4 and 5).

Study objective

Visual outcome in CSR patients is superior when treated by Photodynamic Therapy (PDT) compared to observation.

Study design

Baseline, 3 months, 6 months.

Intervention

Photodynamic therapy (PDT) versus observation. In
the observational arm, patients with persistent lesions at 3 months will be treated with PDT in agreement with current standard of care.

PDT: Visudyne is applied intravenous. After several minutes, the visudyne has reached the retina. When beaming the retina, a photochemical reaction takes place which destroys the neovascularisation.

Contacts

Public
Oogziekenhuis Rotterdam,
Schiedamsevest 180,

T. Missotten
Rotterdam 3011 BH
The Netherlands
010 401777
Scientific
Oogziekenhuis Rotterdam,
Schiedamsevest 180,

T. Missotten
Rotterdam 3011 BH
The Netherlands
010 401777

Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. Informed consent;

3. Poor prognositic acute CSR.

Exclusion criteria

1. History of CSR in either eye;

2. Allergy to fluorescein dyes;

3. Allergy to visudyne;

4. Opaque ocular media, impairing regular fundus imaging;

5. Other ocular disorder possibly reducing visual acuity.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2010
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	26-03-2010
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	NL2137
NTR-old	NTR2261
Other	Oogziekenhuis Rotterdam / MEC : 2009-26 / 2007-105 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Missotten TOAR, Hoddenbach JG, Eenhorst CAE, van den Born LI, Martinez Ciriano JP, Wubbels RJ. A randomized clinical trial comparing prompt photodynamic therapy (PDT) with three months observation in patients with acute central serous chorioretinopathy (CSC) with central macular leakage, Eur J Ophthalmol, [Epub].
PMID: 32264706