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

Published: 24-12-2009
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To determine the outcome in CSR patients comparing treatment with PDT versus observation.

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

Summary

ID

NL-OMON45189

Source
ToetsingOnline

Brief title
CSR & PDT

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
central serous retinopathy

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Keyword: central serous retinopathy, photodynamic therapy, poor prognostic factors

Outcome measures

Primary outcome

Visual acuity at 1 year.

Secondary outcome

Metamorphopsia, color vision, recurrence, presence of persistent subretinal

fluid on OCT, lesion size on autofluorescence imaging.

Study description

Background summary

There is no agreement concerning the early treatment of central serous retinopathy (CSR). In literature, clinical case series using 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.

Study objective

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

Study design

Prospective randomized controlled trial.

Intervention

PDT versus observation.

Study burden and risks

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).

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
Rotterdam 3011 BH
NL
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
Rotterdam 3011 BH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age > 18 years.
Informed consent.

Poor prognositic acute CSR.

Exclusion criteria

History of CSR in either eye.
Allergy to fluorescein dyes.
Allergy to visudyne.
Opaque ocular media, impairing regular fundus imaging
Other ocular disorder possibly reducing visual acuity

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-08-2010
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Visudyne
Generic name:	verteporfine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-12-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-03-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-05-2017
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-017959-98-NL
CCMO	NL30929.078.09