# Pred Forte® in chronic central serous chorioretinopathy

Published: 28-03-2022
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This study has been transitioned to CTIS with ID 2024-511575-15-00 check the CTIS register for the current data. The main objective is the measure the effect on subretinal and intraretinal fluid in severe cCSC calculated by the cumulative areas of...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Retina, choroid and vitreous haemorrhages and vascular disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51739

**Source**
ToetsingOnline

**Brief title**
PICS Trial

### Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

**Synonym**
central serous chorioretinopathy, CSC

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** aanvraag loopt nog bij Rotterdamse Stichting Blindenbelangen

## Intervention

**Keyword:** chronic central serous chorioretinopathy, subretinal fluid, topical steroids

## Outcome measures

### Primary outcome

To investigate whether PF® topical eye drops lead to a reduction of

intraretinal and subretinal fluid after 4 weeks in comparison to placebo eye

drops. Treatment response is objectified by OCT

### Secondary outcome

Secondary endpoints in this study are changes in best-corrected visual acuity

and changes on multimodal imaging.

# Study description

### Background summary

Severe chronic central serous chorioretinopathy (cCSC) is a disease part of the pachychoroid disease spectrum and is characterized by the presence of subretinal and intraretinal fluid. Left untreated these patients are at serious risk of irreversible vision loss. The only effective treatment is photodynamic therapy (PDT), which is expensive and invasive and currently unavailable. It is well-known that pachychoroid diseases can be induced by the use of systemic steroids or an increase in cortisol (stress related). We have seen a strikingly good effect on sub- and intraretinal fluid in other diseases that are part of the pachychoroid disease spectrum by using topical steroidal eye drops. Our hypothesis is that there is a disbalance in systemic versus intraocular steroids. If systemic steroids cannot be lowered a local increase of steroids in the involved eye may restore the intraocular-extraocular steroid balance. A topical steroidal eye drop would be a great, cheap and easy to self-administer alternative treatment to the expansive and invasive PDT therapy

### Study objective

This study has been transitioned to CTIS with ID 2024-511575-15-00 check the CTIS register for the current data.

The main objective is the measure the effect on subretinal and intraretinal fluid in severe cCSC calculated by the cumulative areas of fluid objectified on optical coherence tomography (OCT). Secondary objectives are to gain insight in the mechanism of action through multimodal imaging and to investigate the effect of topical steroids on the intraocular pressure (IOP).

### Study design

A pilot study in which we will assess the effect on fluid in a randomized placebo-controlled study. This moisture can be easily detected (and the surface area can be calculated well) with an OCT scan of the retina. We aim to include 20 patients with cCSC in each arm. The duration of the study is 4 weeks. These patients have chronic fluid in or below the retina, and these 4 weeks will therefore not have a lasting negative effect on the retina, in the absence of a positive response. There is currently no alternative treatment for these patients.

### Intervention

cCSC patients will be treated with Pred Forte® (PF®) eye drops or with placebo eye drops 3 times a day for 4 weeks

### Study burden and risks

All patients will undergo multimodal imaging before inclusion and at the end point of the study, this includes invasive studies. All studies are part of the regular clinical work-up for cCSC and no additional (invasive) investigations will be performed.
The use of PF® holds the risk of an increasement of intraocular pressure (IOP) and may induce cataract. However, both these risks are neglectable when used for 4 weeks only and outweighs the possible reductive effect of PF® on subretinal and intraretinal fluid.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Diagnosis of severe chronic central serous chorioretinopathy that meets the criteria outlined in section 6.1 of protocol
- 18 years or older
- doesn*t meet any exclusion criteria, is willing to sign the consent form
- able to self-administer eye drops.

## Exclusion criteria

- evidence of another retinal diagnoses, such as exudative age-related macular degeneration, suspicion of secondary choroidal neovascularization, polypoidal choroidal vasculopathy, multifocal choroiditis, retinal vascular occlusions, pseudoxanthoma elasticum, amblyopia, and severe myopia (more than *6 dioptres).
- women that are breast feeding or pregnant

# Study design

## Design

Study phase: 3

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

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 19-02-2023 |
| Enrollment: | 40 |
| Type: | Actual |

### Medical products/devices used

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| Product type: | Medicine |
| Brand name: | prednisolone |
| Generic name: | Pred Forte |
| Registration: | Yes - NL outside intended use |

## Ethics review

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| Approved WMO Date: | 28-03-2022 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 04-05-2022 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 12-11-2022 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO | |

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| Date: | 27-12-2022 |
| 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 |
|---|---|
| EU-CTR | CTIS2024-511575-15-00 |
| EudraCT | EUCTR2022-000338-41-NL |
| CCMO | NL80471.091.22 |