

# Posture or Patching (PoP). Accelerated clearing of the media with massive vitreous hemorrhage and suspected retinal tear.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20869

### Source

NTR

### Brief title

PoP

### Health condition

Vitreous hemorrhage.

## Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam

PO Box 70030

3000 LM Rotterdam

**Source(s) of monetary or material Support:** Stichting Wetenschappelijk Onderzoek Oogziekenhuis &#65533; Prof. Dr. Flieringa (SWOO)

## Intervention

## Outcome measures

### Primary outcome

1. Visibility of the superior retinal hemisphere at 20 h. (For the purpose of this study, visibility of the superior retina is defined as 4 clock hours or better);
2. Number of clock hours that is sufficiently visible;
3. Time interval between assuming prescribed posture and ophthalmoscopic examination on the day after presentation;
4. Use of anticoagulant drugs.

### Secondary outcome

N/A

## Study description

### Background summary

Rationale:

About 30-40% of the cases of vitreous hemorrhage are, supposedly, caused by posterior vitreous detachment (PVD) and retinal breaks. Diagnostics are complicated because a sufficiently dense vitreous hemorrhage obstructs the ophthalmologist's fundoscopic inspection, and detection of a retinal tear by ultrasonographic examination is not sufficiently reliable. Therefore, the choice between instant vitrectomy, delayed vitrectomy or regular monitoring remains erratic. If no (initial) signs of retinal tear or detachment are observed, the patient is instructed to restrict physical activity and maintain an upright position, and to return for periodic evaluation. This observational policy may, however, lead to a delay of treatment and an increased risk of developing retinal detachment which may result in a relatively poor outcome. It is conjectured that binocular occlusion accelerates the clearing of an obscured fundus.

Objective:

To investigate whether binocular patching in combination with posture adherence is superior to posture adherence alone in achieving visualization of the superior fundus quadrants or not.

Study design:

Randomized, open-label trial.

Study population:

Patients with vitreous hemorrhage obstructing retinal visibility.

Intervention:

Instruction to maintain posture (group 1 & 2) and binocular patching (group 2).

Main study parameters/endpoints:

Visibility of the superior retinal hemisphere.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients assigned to group 2 will be subjected to regular treatment. They will neither benefit nor be exposed to any extra risk. Patients assigned to group 1 may experience patching of their eyes for up to 24 hours, although not involving any risk, as rather inconvenient. If the probability of fundus visibility increases, and an accurate diagnosis is established earlier, this would be beneficial.

## **Study objective**

Binocular patching in combination with posture adherence is superior to posture adherence alone in achieving visualization of the superior fundus quadrants following a vitreous hemorrhage.

## **Study design**

1. Admittance to the hospital;
2. Next morning.

Time interval between presentation & ophthalmoscopic examination is 12-24 hours.

## **Intervention**

Group 1:

1. Instructions to maintain posture, i.e. in a sitting position at an angle of 45°, and;
2. Binocular occlusion.

Group 2:

1. Instructions to maintain posture, i.e. in a sitting position at an angle of 45°.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

1. Age  $\geq$  18 years;
2. Informed consent;
3. Vitreous hemorrhage (of spontaneous origin) totally obstructing visibility of the retina;
4. Suspicion of a retinal tear.

### Exclusion criteria

1. Retinal detachment (as demonstrated by ultrasonography);
2. Diabetic retinopathy;
3. Retinal venous occlusion;
4. Allergy for eye bandage.

## 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):	01-01-2010
Enrollment:	80
Type:	Actual

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion	
Date:	23-11-2009
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	NL2000
NTR-old	NTR2117
Other	OZR / MEC : 2009-07 / 2009-367
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

van Etten PG, van Overdam KA, Reyniers R, Veckeneer M, Faridpooya K, Wubbels RJ, Manning S, La Heij EC, van Meurs JC. STRICT POSTURING WITH OR WITHOUT BILATERAL PATCHING FOR POSTERIOR VITREOUS DETACHMENT-RELATED VITREOUS HEMORRHAGE.

Retina. 2020; 40(6): 1169-1175.

PubMed PMID: 31136460.