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

Gepubliceerd: 23-11-2009 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20869

Bron
NTR

Verkorte titel
PoP

Aandoening

Vitreous hemorrhage.

Ondersteuning

Primaire sponsor: Oogziekenhuis Rotterdam
PO Box 70030
3000 LM Rotterdam
Overige ondersteuning: Stichting Wetenschappelijk Onderzoek Oogziekenhuis &#65533; Prof. Dr. Flieringa (SWOO)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 funduscopic 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 visiblilty.

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 upto 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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Admittance to the hospital;

2. Next morning.

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

Onderzoeksproduct en/of interventie

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°.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ¡Ý 18 years;

2. Informed consent;

3. Vitreous hemorrhage (of spontaneous origin) totally obstructing visiblilty of the retina;

4. Suspicion of a retinal tear.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Retinal detachment (as demonstrated by ultrasonography);

2. Diabetic retinopathy;

3. Retinal veinous occlusion;

4. Allergy for eye bandage.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	23-11-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2000
NTR-old	NTR2117
Ander register	OZR / MEC : 2009-07 / 2009-367
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
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.