

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Visual outcomes and prognostic factors following pars plana vitrectomy for vitreous haemorrhage in patients with diabetic retinopathy

#### Protocol summary

##### Study aim

The aim of the study was to evaluate pre-operative, intra-operative and post-operative factors which may influence visual gain after vitrectomy for non-clearing vitreous haemorrhage (VH) in patients with severe proliferative diabetic retinopathy (PDR).

##### Design

A single arm group, 172 eyes of 143 patients, non-randomised, single center.

##### Settings and conduct

The study was conducted at the Clinic of Ophthalmology, Emergency County Hospital, Cluj-Napoca, Romania. A single surgeon performed 3-port 23 gauge transconjunctival sutureless vitrectomy. Depending on the situation, aspiration of the VH, peeling or dissection of the tractional membranes was carried out. If needed, retinal endolaser (panretinal photocoagulation PRP or laser completion) was performed. Phacoemulsification with intraocular lens insertion and PPV were combined when the lens opacification prevented the visualization of the posterior segment. At the end of surgery, the vitreous cavity was left under Ballance Salt Solution (BSS), air or silicone oil 1000cSt. Some of the patients underwent a single injection of IVB, 3.8 days prior to PPV. After sterile preparation and draping, 1.25mg/0.05 ml Bevacizumab (Avastin, Genetech) were injected intravitreally in the operating theatre, under topical anaesthesia. Topical antibiotic (tobramycine) was started in the same day and was continued for 5 days post injection.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: pars plana vitrectomy(PPV) for non-clearing diabetic VH for more than a month. Exclusion criteria: follow-up for less than 3 months.

##### Intervention groups

Intervention consisted in pars plana vitrectomy (removal of the vitreous body).

##### Main outcome variables

Postoperative best corrected visual acuity Frequency of

early onset and late onset postoperative hemorrhage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200312046750N1**

Registration date: **2020-03-26, 1399/01/07**

Registration timing: **retrospective**

Last update: **2020-03-26, 1399/01/07**

Update count: **0**

##### Registration date

2020-03-26, 1399/01/07

##### Registrant information

##### Name

Ioana Damian

##### Name of organization / entity

Iuliu Hatieganu University of Medicine and Pharmacy

##### Country

Romania

##### Phone

+40 359 807 824

##### Email address

ioana.damian@umfcluj.ro

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2012-01-01, 1390/10/11

##### Expected recruitment end date

2018-01-01, 1396/10/11

##### Actual recruitment start date

2012-01-01, 1390/10/11

##### Actual recruitment end date

2018-01-01, 1396/10/11

**Trial completion date**

2018-01-01, 1396/10/11

**Scientific title**

Visual outcomes and prognostic factors following pars plana vitrectomy for vitreous haemorrhage in patients with diabetic retinopathy

**Public title**

Vitrectomy for diabetic vitreous hemorrhage

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Non clearing vitreous hemorrhage for more than a month  
Severe diabetic retinopathy Treatment: pars plana vitrectomy Single surgeon experience

**Exclusion criteria:**

Follow-up less than 3 months Other macular diseases, advanced glaucoma History of ocular trauma History of pars plana vitrectomy for tractional retinal detachment

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **130**

More than 1 sample in each individual

Number of samples in each individual: **2**

2 eyes/patient if both eyes have PDR

Actual sample size reached: **143**

More than 1 sample in each individual

Actual sample size in each individual: **2**

172 eyes of 141 patients

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of the "Iuliu Hatieganu" University of Medicine and Pharmacy

**Street address**

No.8, Victor Babes

**City**

Cluj-Napoca

**Postal code**

400012

**Approval date**

2020-03-24, 1399/01/05

**Ethics committee reference number**

131

**Health conditions studied****1****Description of health condition studied**

Diabetic retinopathy

**ICD-10 code**

E08.35

**ICD-10 code description**

Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy

**Primary outcomes****1****Description**

Postoperative best corrected visual acuity(BCVA)

**Timepoint**

3 months after pars plana vitrectomy

**Method of measurement**

Measurement of the visual acuity using Snellen chart

**2****Description**

Frequency of postoperative early and late vitreous hemorrhage

**Timepoint**

Early onset: < 4 weeks and late onset > 4 weeks

**Method of measurement**

Slit lamp and ophthalmoscopy

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention consisted in pars plana vitrectomy (removal of the vitreous body). If needed, retinal endolaser (panretinal photocoagulation PRP or laser completion) was performed. Phacoemulsification with intraocular lens insertion and PPV were combined when the lens opacification prevented the visualization of the posterior segment. At the end of surgery, the vitreous cavity was left under Ballance Salt Solution (BSS), air or silicone oil 1000cSt

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Clinic of Ophthalmology, Emergency County Hospital

**Full name of responsible person**

Ioana Damian

**Street address**

No.3-5, Clinicilor street

**City**

Cluj-Napoca

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400006

**Phone**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

University of Medicine and Pharmacy „Iuliu Hatieganu"

**Full name of responsible person**

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**Street address**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

University of Medicine and Pharmacy „Iuliu Hatieganu"

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

„Iuliu Hatieganu" University of Medicine and Pharmacy

**Full name of responsible person**

Ioana Damian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ophthalmology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

„Iuliu Hatieganu" University of Medicine and Pharmacy

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Because of the confidentiality of the information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available