

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

Postal code

400006

Phone

+40 264 597 852

Email

ioana.damian@umfcluj.ro

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

University of Medicine and Pharmacy „Iuliu Hatieganu"

Full name of responsible person

Ioana Damian

Street address

No.8 Victor Babes

City

Cluj-Napoca

Postal code

400012

Phone

+40 264 597 256

Email

ioana.damian@umfcluj.ro

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

Street address

No.8 Victor Babes

City

Cluj-Napoca

Province

Cluj

Postal code

400012

Phone

+40 264 597 256

Email

ioana.damian@umfcluj.ro

Person responsible for scientific 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

Street address

No.8 Victor Babes

City

Cluj-Napoca

Province

Cluj

Postal code

400012

Phone

+40 264 597 256

Email

ioana.damian@umfcluj.ro

Person responsible for updating data**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

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400012

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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