

“23-Gauge Vitrectomy, Endolaser, and Gas Tamponade” versus “Vitrectomy alone” for the Management of ‘Serous Macular Detachment Associated with Optic Disc Pit’

Submission date 05/07/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/07/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/11/2015	Condition category Eye Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

This is an observational study. The aim is to compare a ‘23-gauge pars plana vitrectomy (PPV), endolaser, and gas tamponade’ approach versus a ‘vitrectomy alone’ for the management of serous macular detachment associated with optic disc pits. We want to find out about the following questions: Are there differences in the postoperative visual acuity and the postoperative central foveal thickness between two groups? What is the mean time of the postoperative subretinal fluid resolution in both groups? Is there correlation between the preoperative features of the inner/outer segment junction with improvement of postoperative visual acuity?

We would like to show that there a difference between the vitrectomy alone and the combined surgery.

Who can participate?

Patients with Phakic intraocular lens (a special kind of lens) and erous macular detachment associated with optic disc pits.

What does the study involve?

All participants undergo a complete ophthalmological examination - visual acuity, intraocular pressure with applanation tonometry, biomicroscopic examination findings, dilated pupil examination of the posterior segment, optic coherence tomography (OCT), and fundus autofluorescence done – a the begininf were evaluated at baseline and during follow-up period. Some participants have the 23-gauge PPV, endolaser, and gas tamponade procedure, while others only have the 23-gauge PPV procedure.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Ankara Ulucanlar Eye Education and Research Hospital (Turkey)

When is the study starting and how long is it expected to run for?

January 2008 to December 2015.

Who is funding the study?

Ankara Ulucanlar Eye Education and Research Hospital (Turkey)

Who is the main contact?

Dr Mehmet Citirik

Contact information

Type(s)

Scientific

Contact name

Dr Mehmet Citirik

Contact details

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Ankara

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06230

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

"23-Gauge Vitrectomy, Endolaser, and Gas Tamponade" versus "Vitrectomy alone" for the Management of 'Serous Macular Detachment Associated with Optic Disc Pit': a comparative case control study.

Study objectives

Are there differences between the clinical outcomes of "23-gauge vitrectomy, endolaser, and gas tamponade" versus "vitrectomy alone" for the management of serous macular detachment associated with optic disc pits?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Diskapi Training and Research Hospital, 21/04/2014, reference 15/12

Study design

Retrospective comparative case-controlled study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Optic disc pits (rare congenital anomaly with a reported incidence of one in 11,000 patients)

Interventions

Some eyes underwent 23-gauge PPV, endolaser, and gas tamponade (allocated to Group 1) and some eyes underwent 23-gauge vitrectomy alone (allocated to Group 2). Consecutive cases underwent combined surgery and other consecutive cases underwent vitrectomy alone. All cases were phakic and had serous retinal detachment.

Intervention Type

Other

Primary outcome(s)

Differences in the postoperative visual acuity and the postoperative central foveal thickness between the two groups.

The main outcome measure was change in best-corrected visual acuity and correlation between best-corrected visual acuity and spectral-domain optical coherence tomography.

Key secondary outcome(s)

Differences in the mean time of the subretinal fluid resolution between the two groups.

Completion date

31/12/2015

Eligibility

Key inclusion criteria

All cases were phakic and had serous macular detachment associated with optic disc pits.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients with a history of prior Pars plana vitrectomy (PPV) surgery and any corneal pathology.

Date of first enrolment

01/01/2008

Date of final enrolment

31/07/2015

Locations

Countries of recruitment

Türkiye

Study participating centre

Ankara Ulucanlar Eye Education and Research Hospital

Ankara

Türkiye

06230

Sponsor information

Organisation

Ankara Ulucanlar Eye Education and Research Hospital

ROR

<https://ror.org/045d4f586>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Ankara Ulucanlar Eye Education and Research Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2015		Yes	No