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“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

Registration date
22/07/2015

Overall study status
Completed

Last Edited
04/11/2015

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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, biomicroscobic 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 of 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 measure
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.

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

Overall study start date
01/01/2008

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

Age group
Adult

Sex
Both

Target number of participants
5-10

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

Sponsor details
Ulucanlar Cad. No: 59 Altindag
Ankara
Türkiye
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/045d4f586

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ankara Ulucanlar Eye Education and Research Hospital

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/08/2015

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