Matrix metalloproteinases and their tissue inhibitors after selective laser trabeculoplasty in pseudoexfoliative secondary glaucoma

Submission date Recruitment status Prospectively registered 13/03/2008 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 20/03/2008 Completed [X] Results [] Individual participant data Last Edited Condition category 30/12/2020 **Eve Diseases**

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Matrix metalloproteinases and their tissue inhibitors after selective laser trabeculoplasty in pseudoexfoliative secondary glaucoma

Study objectives

Pseudoexfoliative glaucoma (PEXG) is a degenerative fibrillopathy characterised by the production and accumulation of extracellular fibrillar material not just in the anterior segment of the eye, but also in numerous extraocular tissues. At an ocular level, there is atrophy of the iris dilator muscle fibre cells, degeneration of the irideal pigment with dispersion of melanin, peripupillar atrophy and an increase in the trabecular meshwork pigmentation. A typical feature is the excessive accumulation of the extracellular matrix material in the juxtacanalicular tissue. This accumulation explains the increased resistance to aqueous outflow found in eyes with PEXG.

Study aim:

To assess the variations in the metalloproteinases (MMP-2) and tissue inhibitor of metalloproteinases (TIMP-2) values following selective laser trabeculoplasty (SLT) in patients with pseudoexfoliative glaucoma (PEXG).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Institutional Ethics Committee of the St Orsola Malpighi University Hospital, University of Bologna on the 24th October 2007 (ref: 2007-007744-98).

Study design

Observational, open, single centre, case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pseudoexfoliative secondary glaucoma

Interventions

Arm 1: Patients with pseudoexfoliative glaucoma with good intraocular eye pressure (IOP) control and cataract (15 patients). These patients received cataract surgery only. Arm 2: Patients with pseudoexfoliative glaucoma only that undewent selective laser trabeculoplasy (SLT) without good control of IOP (15 patients). These patients received SLT, and after one month surgical trabeculectomy.

Arm 3 (control group): Patients with catarct only (15 patients). These patients received catarct surgery only.

Selective laser trabeculoplasty (SLT) was performed with Selecta 7000 (Q switched, frequency doubled, 532 Nd:YAG laser) using 50 non-overlapping applications in the inferior 180° of the trabecular meshwork, with a spot size of 400 µm and pulse duration of 3 ns. Aqueous humour was aspirated during surgery from patients.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

MMP-2 and TIMP-2 concentration, assessed once during the cataract surgery in Arm 1 and 3, and during trabeculectomy in Arm 2.

Secondary outcome measures

Intraocular pressure, measured before surgery and 7, 15 days and one month after surgery in all three arms of participants.

Overall study start date

13/02/2006

Completion date

15/06/2006

Eligibility

Key inclusion criteria

Fifteen patients with pseudoexfoliative glaucoma and cataract, and 15 patients with pseudoexfoliative glaucoma (30 patients in total):

- 1. Patients of either gender
- 2. Aged from 58 74 (in all three arms)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

45

Total final enrolment

30

Key exclusion criteria

- 1. Pseudophachia
- 2. Non-pseudoexfoliative glaucoma
- 3. History of laser treatment

Date of first enrolment

13/02/2006

Date of final enrolment

15/06/2006

Locations

Countries of recruitment

Italy

Study participating centre

Via Massarenti, 9

Bologna Italy

40138

Sponsor information

Organisation

University of Bologna (Italy)

Sponsor details

Department of Surgery and Anaesthesiology Science Ophthalmology Service Via Massarenti, 9 Bologna Italy 40139

Sponsor type

University/education

Website

http://www.eng.unibo.it/PortaleEn

ROR

https://ror.org/01111rn36

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St Orsola Malpighi University Hospital Bologna (Italy)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/10/2008	30/12/2020	Yes	No