ISRCTN79745214 https://doi.org/10.1186/ISRCTN79745214

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mauro Cellini

Contact details
Via Massarenti, 9
Bologna
Italy
40138

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