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Perforated punctal plug as an alternative to the three snip punctoplasty for the treatment of acquired lacrimal punctum stenosis

Submission date
14/08/2017

Recruitment status
No longer recruiting

Registration date
12/09/2017

Overall study status
Completed

Last Edited
10/09/2018

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Acquired punctal stenosis is a condition whereby the hole that drains the tears, the punctum, gets blocked leading to watery eyes. This can have a significant impact on someone's quality of life, like difficulties in performing everyday activities and temporary impairment of vision. There are a number of treatment options available to open up the punctum and drain the tears. The conventional treatment for this condition is a three-snip punctoplasty, which involves having a small operation to surgically enlarge the punctum. This is the procedure that is routinely offered to patients at our hospital. More recently, a “plug” has been developed that stretches the punctum. It is placed in the punctum and stays there for two months and is then removed. The plug is safe and is licensed for this use. Most people are not aware of it when it is in place. The advantage of the plug is that it does not involve cutting open the punctum, i.e. it avoids having an operation, so it is a smaller procedure and is less invasive. It is also reversible and does not preclude having the operation at a later stage. The aim of this research study is to compare the two treatment options to assess whether the perforated punctal plugs and three-snip procedures are similarly effective. We will assess the outcome of each in terms of impact on quality of life as well amount of watering after procedures.

Who can participate?
Adults aged 18 and older who have acquired punctual stenosis of the lower eyelid.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the plug treatment. The plugs are removed after two months. Those in the second group receive the 3-snip procedure. All participants attend a follow up appointment at six months and receive a telephone call after 12 months to assess the severity of participant’s watery eyes.

What are the possible benefits and risks of participating?
There are no direct benefits with participating. Those in the punctual plug group require a extra follow-up visit to the clinic to remove the plug. Participants receive a follow up telephone one year after the procedure to see if there is any illness or discomfort during the study.

Where is the study run from?
Western Eye Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2014 to January 2020

Who is funding the study?
The British Oculoplastic Surgery Society (BOPSS) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35158

Study information

Scientific Title
Perforated Punctal Plug as an alternative to the three snip punctoplasty for the treatment of acquired lacrimal punctum stenosis: the POPPY study

Study objectives
The aim of this study is to determine if perforated punctal plugs are an acceptable alternative to 3-snip punctoplasty in the treatment of acquired punctal stenosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Central Research Ethics Committee, 20/07/2017, ref: 17/LO/1003

Study design
Randomised; Interventional; Design type: Treatment, Diagnosis, Device, Imaging, Surgery

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Ophthalmology, Primary sub-specialty: Other; UKCRC code/ Disease: Eye/ Other disorders of eye and adnexa

Interventions
Randomisation is computer generated sequential binary randomisation in blocks of 10.

Punctal plugs treatment arm:
Perforated punctal plugs, coated with a thin layer of polyvinylpyrrolidone (PVP) silicone (FCI Ophthalmics), are available as 0.7mm and 0.9mm devices. Since the puncta they are used in are by definition stenosed, the 0.7mm size is suitable in most cases. These are inserted under topical anaesthesia (0.5% proxymetacaine) or local anaesthesia as described for 3-snip punctoplasty above. As in the 3-snip procedure, the first step is punctal dilatation; with the lower eyelid on lateral stretch, the punctum and proximal canaliculus is dilated with a Nettleship dilator. The PPP is inserted soon after dilatation. The inserter is held between the thumb and index finger, and the plug is orientated in the correct plane. The plug is introduced gently in a vertical and progressive manner. The plug is released from the inserter by depressing the inserter handle. Attention is given to the final position of the plug to achieve an optimal fit against the lid margin.

3-snip procedure:
The 3-snip procedure, is performed as follows. Local anaesthetic (such as xylocaine 1% with 1:

200,000 adrenaline) is injected inferior to the punctum (transcutaneously and/or transconjunctivally). With the lower eyelid on lateral stretch, the punctum and proximal canaliculus is dilated with a Nettleship dilator. A blade or fine scissors are used to make a vertical cut through the posterior aspect of the proximal canaliculus. The proximal horizontal portion of the canaliculus (less than one third of the length) is then opened using the blade / scissors. Finally, a small posterior lamellar triangle of conjunctiva and canaliculus is removed.

Treatment is a once-only surgical procedure. The plugs are removed at two-months. Each arm is reviewed in person at six months and then by telephone follow-up at 12 months.

Intervention Type
Other

Primary outcome measure
Estimated number of times eye has watered in the past week, as assessed by questions 2 and 3 in the Imperial Watery Eye Quality of Life Questionnaire at baseline, 6 months and 12 months

Secondary outcome measures
1. Effect of watering on quality of life, assessed on an 11-point numerical rating scale as part of the watery eye quality of life questionnaire (Appendix 6), at 12 months post procedure; in the case of PPPs this will be 12 months post plug removal.
2. Slit lamp examination of punctum. A punctum size of Grade 3-5, as defined on the visual grading system by Kashkouli et al, (Appendix 4) will be considered successful
3. Slit lamp examination of tear meniscus. A tear meniscus greater than 0.3mm will be considered raised, a secondary measure of anatomical failure.
4. OCT of lacrimal punctum. There are not sufficient normative databases in the literature to use as a reference but we will compare figures pre- and post-operatively to assess the effect of the treatments and to assess the utility of OCT as a tool for analysing puncta

Overall study start date
14/06/2014

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Age ≥ 18 years (men and women)
2. Epiphora as a result of acquired punctal stenosis of lower lids
3. Full patency on lacrimal syringing
4. Willing to undergo a procedural intervention
5. Willing and able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. History of congenital punctal stenosis
2. History of punctal stenosis associated with chemotherapy
3. Completely stenosed or occluded punctum
4. Abnormality on lacrimal syringing
5. Moderate or severe lower eyelid laxity or eyelid malposition
6. Use of eye drops, other than lubricants, within the past 3 months or planned in the study eye during the course of the trial
7. Eyelid or ocular surgery within the past 3 months or planned surgery in the study eye, during the course of the trial
8. Planned chemotherapy during the course of the trial
9. Planned nasal or sinus surgery during the course of the trial
10. Any other condition or situation that, in the opinion of the investigator, may prevent the participant complying with the study or follow-up procedures

Date of first enrolment
04/09/2017

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Western Eye Hospital
153-173 Marylebone Road
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Sponsor information

Organisation
Imperial College Healthcare NHS Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Research organisation

Funder Name
The British Oculoplastic Surgery Society (BOPSS)

Results and Publications

Publication and dissemination plan
It is intended that the results of the study will be reported and disseminated at an international conference and published in a high-impact peer-reviewed scientific journal.

Intention to publish date
28/02/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No