ISRCTN74335571 https://doi.org/10.1186/ISRCTN74335571

Prospective randomised controlled study comparing endonasal dacrocystorhinostomy conducted with and without potassium titanyl phosphate (KTP) laser for patients demonstrated to have nasolacrimal duct obstruction

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2008	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0106101574

Study information

Scientific Title

Study objectives
To investigate whether the different endonasal techniques currently used in dacrocystorhinostomy (DCR) demonstrate any benefit to patients either in the surgical outcome or acceptability of the procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Endonasal dacrocystorhinostomy

Interventions
1. Laser endonasal dacrocystorhinostomy
2. Dissection endonasal dacrocystorhinostomy

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. Patient acceptability of the procedure
2. Symptomatic reduction in epiphoria
3. Assessment of complication rates
4. Frequency of stenosis leading to recurrence of symptoms

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/07/2001

Completion date
31/07/2003

Eligibility

Key inclusion criteria
100 patients who have nasolacrimal duct obstruction

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
10/07/2001

Date of final enrolment
31/07/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Director of ENT Department
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GL1 3NN

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Gloucestershire R&D Consortium (UK)

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	01/12/2007		Yes	No