

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 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol ☐ Statistical analysis plan ☒ Results ☐ Individual participant data
Registration date 12/09/2003	Overall study status Completed	
Last Edited 17/12/2008	Condition category Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/07/2003

Eligibility

Key inclusion criteria

100 patients who have nasolacrimal duct obstruction

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Clinical Director of ENT Department

Gloucester

United Kingdom

GL1 3NN

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Gloucestershire R&D Consortium (UK)

Results and Publications

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