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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

Contact name
Miss Kate Evans

Contact details
Clinical Director of ENT Department
ENT Department
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

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

Study design
Randomised controlled trial

Primary study design
Interventional

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