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Evaluation of cutting balloons for treatment of salivary duct strictures

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 28/07/2017	**Condition category** Digestive System	

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
N0013145948

Study information

Scientific Title
Evaluation of cutting balloons for treatment of salivary duct strictures

Study objectives
Are cutting balloons more effective than conventional angioplasty balloons for treating salivary duct strictures?

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Salivary duct stenosis

Interventions
A randomised controlled trial comparing the use of conventional balloons used for the treatment of salivary stenosis versus cutting balloons.

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical evaluation and radiological (sialogram) follow up

Secondary outcome measures
Not provided at time of registration

Overall study start date

01/06/2003

Completion date
01/12/2005

Eligibility

Key inclusion criteria
All patients requiring treatment for salivary obstruction due to stenosis.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
25

Key exclusion criteria
1. Any patient suffering from an acute or chronic systemic illness that renders them unsuitable for elective outpatient dental treatment under local anaesthesia
2. Pregnant women
3. Patients exhibiting signs or symptoms of acute infection of the salivary gland under examination
4. Patients with an allergy to iodine (as in radiographic contrast agents) or local anaesthetic agents

Date of first enrolment
01/06/2003

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Guy's Hospital
London
United Kingdom
SE21 9RT

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Guy's and St. Thomas' NHS Foundation Trust (UK)

Funder Name
Own account

Funder Name
NHS R&D Support Funding (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