ISRCTN91891418 https://doi.org/10.1186/ISRCTN91891418

# Evaluation of cutting balloons for treatment of salivary duct strictures

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|---|---|---|
| **Submission date**<br>30/09/2005 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>28/07/2017 | **Condition category**<br>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
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

**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