

Evaluation of cutting balloons for treatment of salivary duct strictures

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

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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Clinical evaluation and radiological (sialogram) follow up

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/12/2005

Eligibility**Key inclusion criteria**

All patients requiring treatment for salivary obstruction due to stenosis.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Guy's Hospital

London

United Kingdom

SE21 9RT

Sponsor information

Organisation

Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration