

# Comparison of transnasal oesophagoscopy versus standard care for patients presenting with throat symptoms

<b>Submission date</b> 16/03/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/08/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 12/09/2016	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Martin Birchall

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 2.0

# Study information

## Scientific Title

Randomised controlled trial of transnasal oesophagoscopy versus standard care for patients presenting with throat symptoms

## Acronym

TOVSC

## Study objectives

The availability of transnasal oesophagoscopy in secondary care clinics for patients with throat symptoms results in a reduction in overall patient pathway time, reduced adverse events, an improved cost-benefit profile and is viewed as preferable by patients.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Gloucestershire Research Ethics Committee, 08/12/2008, ref: 07/H0105/79

## Study design

Randomised controlled open-label clinical trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Diagnostic

## Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Throat symptoms

## Interventions

Control arm: Standard care

Intervention arm: Otolaryngologist is able to use a trans-nasal oesophagoscope to evaluate patient in addition to all other investigations routinely at his or her disposal in the otolaryngology and other hospital departments

## Intervention Type

Other

**Phase**

Not Applicable

**Primary outcome measure**

Process time, measured from the date of first presentation to the ENT clinic. The process will be said to have ended when the patient has been informed face-to-face of their definitive diagnosis. At this point most patients will be referred back to their general practitioner, or will enter a new pathway, such as treatment for head and neck cancer.

**Secondary outcome measures**

1. Minor adverse events
2. Major adverse events
3. Cost to:
  - 3.1. Health care service
  - 3.2. The patient
  - 3.3. Society, calculated using the human capital approach
4. Quality of life
5. Cost-effectiveness

**Overall study start date**

01/11/2009

**Completion date**

01/12/2010

## **Eligibility**

**Key inclusion criteria**

1. Patients referred to secondary care Ear, Nose and Throat (ENT) services at recruiting centres with throat symptoms
2. Aged 18 years or older
3. Specific symptoms
  - 3.1. Globus pharyngeus
  - 3.2. Dysphagia
  - 3.3. Odynophagia
  - 3.4. Pain in throat
  - 3.5. Foreign body sensation
  - 3.6. Blood stained sputum

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

50 in each arm

**Key exclusion criteria**

1. Patients unable to provide informed consent
2. Patients with large neck mass, raising a strong suspicion that the patient is suffering from a head and neck cancer

**Date of first enrolment**

01/11/2009

**Date of final enrolment**

01/12/2010

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Royal National Throat Nose and Ear Hospital

London

United Kingdom

WC1X 8DA

**Sponsor information****Organisation**

Royal Free Hampstead NHS Trust (UK)

**Sponsor details**

Royal Free Hospital

Pond Street

London

England

United Kingdom

NW3 2QG

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.royalfree.org.uk/>

**ROR**

<https://ror.org/04rtdp853>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Pentax UK Limited (UK) - funding analysis; analysis is being completed independantly by the Courtyard Group.

## **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