

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

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

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Additional identifiers

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Royal National Throat Nose and Ear Hospital

London

United Kingdom

WC1X 8DA

Sponsor information

Organisation

Royal Free Hampstead NHS Trust (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration