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

Submission date 16/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/08/2010	**Overall study status** Completed	
Last Edited 12/09/2016	**Condition category** Ear, Nose and Throat	

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

Primary study design
Interventional

Study design
Randomised controlled open-label clinical trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Throat symptoms

Interventions
Control arm: Standard care
Intervention arm: Otolaryngologist is able to us 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