ISRCTN68055393 https://doi.org/10.1186/ISRCTN68055393

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

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 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 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