ISRCTN69567857 https://doi.org/10.1186/ISRCTN69567857

Determination of quality of life instrument most preferred by head and neck patients

Submission date 09/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/07/2010	**Overall study status** Completed	
Last Edited 18/12/2017	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.inhanse.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HM22-0806

Study information

Scientific Title
Determination of quality of life instrument most preferred by head and neck patients: a multicentre randomised controlled trial

Acronym
DETERMIN

Study objectives
This research project is to identify head and neck cancer patients most preferred questionnaire that will help them communicate and describe problems more effectively with their doctor. The null hypothesis is that the four questionnaires are equally useful in facilitating the communication of health concerns of both laryngeal and oral cancer patients to their health professionals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coventry Local Research Ethics Committee, 13/12/2006, ref: 06/Q2802/101

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Can be found at http://www.inhanse.org

Health condition(s) or problem(s) studied
Early and advanced oral and laryngeal cancer

Interventions

Four questionnaires will be randomised in each pack. Packs are colour coded regarding early or advanced oral or laryngeal cancer. Patients are asked to complete study instrument in clinic while waiting to see their clinicians.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To determine which of four most commonly used head and neck health related quality of life instruments oral and laryngeal cancer patients find most helpful in facilitating communication of their health problems to their clinicians, measured in December 2010.

Secondary outcome measures
To determine the clinical significance of reported health related quality of life changes detected by the commonly used quality of life instruments in head and neck cancer, measured in December 2010.

Overall study start date
21/10/2008

Completion date
29/10/2010

Eligibility

Key inclusion criteria
1. Patients aged greater than 18 years, either sex
2. Diagnosed with oral or laryngeal cancer
3. Attending the head and neck cancer clinic at least 3 months after completion of treatment

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
600 returned questionnaires

Key exclusion criteria
1. Patients who do not have oral or laryngeal cancer
2. Patients who have known recurrence of cancer
3. Patients who are undergoing palliative treatment

Date of first enrolment
21/10/2008

Date of final enrolment
29/10/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
InHANE offices OPP ward 32
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust (UK)

Sponsor details
c/o Ceri Jones
Research and Development Service Manager
University Office Suite, 1st Floor Retunda
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Sponsor type
Hospital/treatment centre

Website
http://www.uhcw.nhs.uk

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Charity

Funder Name
Macmillan Cancer Support (UK)

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