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
Registration date 21/07/2010	Overall study status Completed	 Statistical analysis plan Results
Last Edited 18/12/2017	Condition category Cancer	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website http://www.inhanse.org

Contact information

Type(s) Scientific

Contact name Prof Hisahm Mehanna

Contact details

InHANE offices OPP ward 32 3rd Floor West Wing University Hospitals Coventry and Warwickshire NHS Trust Clifford Bridge Road Walsgrave Coventry United Kingdom CV2 2DX +44 (0)24 76 96 5244 hisham.mehanna@uhcw.nhs.uk

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 Clifford Bridge Road Walsgrave Coventry England United Kingdom CV6 4GJ

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