V1.0

The CONSENSUS Study

Squamous Cell CarcinOma of the OropharyNx: Late PhaSE CliNical TrialS; Core OUtcomeS

Cochrane Colloquium 2013

Background

Patients and those involved in their care are rarely involved in outcome selection in clinical trials. As a result, the outcomes chosen are often not relevant to patients or may have little clinical application. Furthermore, there is no standardisation of outcome selection and reporting, even amongst trials of comparable interventions. This reduces the data available for meta-analyses leading to difficulties in interpreting a treatment's effectiveness and in making evidence based healthcare decisions. Outcome reporting bias has also been highlighted as a significant problem in the healthcare literature (1).

Human Papillomavirus type-16 (HPV) related Oropharyngeal Cancers (OPSCC) have doubled in incidence in the UK over the last decade (2), and this trend is mirrored in other developed countries (3). These cancers occur in a younger patient population than HPV negative cancers, and have vastly better survival outcomes, with five-year survival in some centres reported at >90% (4).

When assessing interventions for the treatment of these cancers, the measurement and reporting of clinically important and patient relevant outcomes is more important than ever, because more patients will live for longer with any side-effects of their treatment (5). It is therefore with some degree of urgency that efforts must be made to establish what the important outcomes are, and to ensure that these are measured.

Objectives

To develop a Core Outcome Set (COS) for OPSCC clinical trials.

Methods

A systematic review will identify which outcomes are reported in OPSCC RCTs. Semi-structured qualitative interviews with patients and their carers will aim to establish which outcomes they deem most important. We will aim to achieve consensus on the contents of the final COS in a Delphi consensus survey and consensus meeting involving major stakeholders.

Results

Outcomes identified through the systematic review will be presented along with the preliminary analysis of the UK interviews.

References

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