Utility of the skin cancer quality of life impact tool (SCQOLIT)

Submission date Recruitment status Prospectively registered 03/02/2016 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 03/02/2016 Completed [X] Results Individual participant data **Last Edited** Condition category 04/01/2021 Cancer

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Public

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT02580916

Protocol serial number

20564

Study information

Scientific Title

Use of the Skin Cancer Quality of Life Impact Tool (SCQOLIT) – a feasibility study in non-melanoma skin cancers

Study objectives

The aim of this study is to explore the practicality and value of the Skin Cancer Quality of Life Impact Tool (SCQOLIT) for non-melanoma skin cancer (NMSC) to patients and clinicians in the dermatology clinical setting.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxford B Research Ethics Committee, 18/06/2015, ref: 14/SC/1446

Study design

Prospective non-randomised study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Cancer, Dermatology; Subtopic: Melanoma, Skin (all Subtopics); Disease: Skin, Dermatology

Interventions

Three hundred patients (100 with squamous cell carcinoma, 200 with basal cell carcinoma) identified in Dermatology outpatient clinics will be recruited to complete SCQOLIT questionnaires at baseline (after histological confirmation of NMSC), at 3 months (by postal or face:face) and at 6-9 months (high risk patients only). Structured interviews with twenty patients and focus group work with 10-15 Dermatology staff will establish acceptability of the SCQOLIT and identify any barriers to implementation. Both quantitative and qualitative analyses will be undertaken.

Intervention Type

Other

Primary outcome(s)

Acceptability of SCQOLIT tool as determined by analysis of patients participation rates and qualitative analysis of patient and staff preferences at the end of the study.

Key secondary outcome(s))

Psychometric properties of SCQOLIT tool are measured at baseline, 3 months and 6-9 months.

Completion date

30/03/2017

Eligibility

Key inclusion criteria

- 1. Aged 18 years or above
- 2. Participant is willing and able to give informed consent for participation in the study.
- 3. All patients with a histopathological diagnosis of NMSC (primary or recurrent disease)
- 4. All treatments used for NMSC will be included in the study; excision, shave excision, curettage and cautery, Mohs micrographic surgery, photodynamic therapy and topical treatments e.g. imiquimod cream

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

318

Key exclusion criteria

- 1. Concurrent internal malignancy as this is likely to significantly influence quality of life (QOL)
- 2. Patients referred on to other specialties for management of their skin cancer e.g. Plastic surgeons / Clinical oncology
- 3. Other significant dermatological diseases e.g. severe inflammatory or blistering skin conditions as this may influence QOL
- 4. Inability to consent for themselves

Date of first enrolment

01/07/2015

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Churchill Hospital

Old Road Headington Oxford United Kingdom OX3 7LJ

Sponsor information

Organisation

Oxford University Hospitals NHS Trust

ROR

https://ror.org/03h2bh287

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Oxfordshire Health Services Research Committee

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	results	01/03 /2020	04/01 /2021	Yes	No
Abstract results	results presented at ISOQOL in :	01/10 /2016	29/04 /2019	No	No
Abstract results	results presented at the 97th Annual Meeting of the British Association of Dermatologists in :	30/11 /2017	29/04 /2019	No	No
HRA research summary			28/06 /2023	No	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes