



Participant Questionnaire

Introduction

Outline of the study

Most squamous cell carcinomas (SCCs) are cut out by a skin surgeon who takes a margin of skin around it which looks normal. The aim is to ensure that all the cancer has been removed whilst maintaining function and the cosmetic appearance of the treated area. Based on the evidence we have available to us at the moment, the British Association of Dermatologists currently recommends that squamous cell cancers that appear to be at low risk of coming back are cut out with a 4mm margin of normal-looking skin around them, and that those cancers which have features making them more likely to come back after treatment are cut out with a 6mm or larger margin. However, there is real uncertainty whether taking a larger margin of apparently normal skin when the cancer is cut out decreases the risk of recurrence.

In addition, some patients receive additional radiotherapy after they have had their SCC cut out, for example those in whom there may be some cancer cells seen around the nerves when it is examined under the microscope, or those in whom there is doubt that all the tumour has been cut out. However, we don't know whether giving radiotherapy after surgery benefits patients in terms of the tumour coming back and longer term survival, nor whether there is group of patients with certain types of SCCs which may benefit particularly from having this extra radiotherapy.

In the study we are proposing, patients whose cancer is considered by their doctor to have features which make it more likely to recur (such as being greater than 2cm in its largest dimension, or invading deeply into the skin, or which are located on the ear or lip), will initially be randomised to have their SCC removed with EITHER:

a 6mm margin of normal looking skin around it

OR

a 10mm margin of normal looking skin around it (See pictures)

Following surgical excision of their SCC, **some** people whose SCCs have certain additional high-risk features would then be eligible to take part in the second stage of the study, this time being randomised to receive EITHER:

additional radiotherapy to the local area

OR

NO additional radiotherapy.

The radiotherapy will be given by a clinical oncologist who has expertise in the use of radiotherapy for skin cancer and will require that the patient visits the hospital as required according to the treatment schedule so that the radiotherapy can be given.

Not everyone who takes part in the first phase of the trial comparing excision margins will be eligible to be randomised into this second radiotherapy phase if their SCC lacks the characteristics in which we are interested.

All participants will be followed up for 5 years to check that their cancer has not come back, regardless of whether they are involved in just the first stage of the study or in both stages.

The study would be 'randomised', which means that a computer would assign participants to have their skin cancer cut out with either a 6mm or 10mm margin, and if eligible for the second phase, to either receive additional radiotherapy or no additional radiotherapy. This means that participants have an equal chance of having a 6mm margin and an equal chance of having a 10mm margin, and if applicable, an equal chance of receiving radiotherapy and an equal chance of not receiving radiotherapy.

No-one involved in their care would know in advance which treatment participants were going to have. This method produces the fairest results.

If you have any questions about this work or there something you would like clarifying, please contact the lead researcher who will be happy to talk to you:

Dr Louise Lansbury

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Kings Meadow Campus,

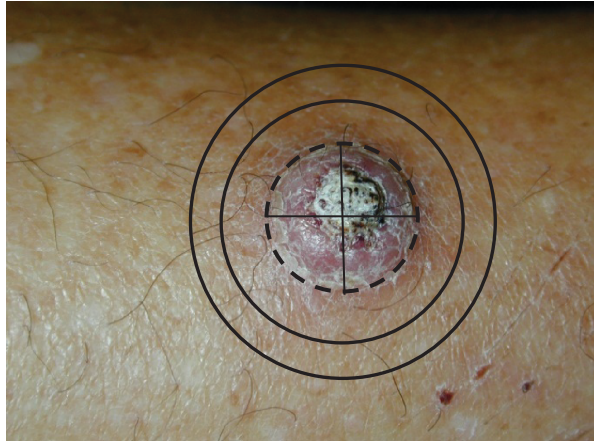
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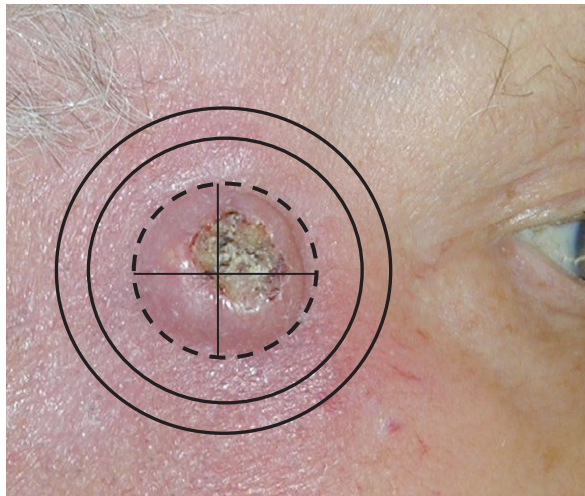
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An example of a 2cm forearm SCC (as outlined by dashed line), and the two excision margins which participants could be randomised to: 6mm (inner solid line) and 10mm (outer solid line).



An example of a 2cm SCC with 6mm (inner solid line) and 10mm (outer solid line) margin of normal-looking skin – temple



Initials:.....

DOB:.....

Participant code:.....

Questionnaire

Please note that we are only seeking your opinions: we are not asking you to take part in the proposed trial itself.

1 - How willing would you be to be randomised into each stage of the proposed trial?

| | <i>Both stages</i> | <i>First stage only</i> (6mm versus 10mm margin) | <i>Second stage only</i> (extra radiotherapy versus No radiotherapy) |
|----------------|---------------------------|--|--|
| Definitely YES | | | |
| Probably YES | | | |
| NOT SURE | | | |
| Probably NOT | | | |
| Definitely NOT | | | |

2 - We would like to find out what **barriers** would prevent patients from being willing to participate in this study. Please explain any reasons why you have responded in this way (no matter how trivial you may think these reasons are) [For example, some of the following may be concerns you have thought of: *having radiotherapy; cosmetic appearance; time of extra visits to hospital; cost of extra visits (transport, parking); transport logistics; carer concerns (time off work, commitment, financial); issues around the trial itself*]; or you may have thought of other things which would prevent your participation in such a study]

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3 Do you have **PREFERENCE** for one of the treatments over the other?

a) SCC cut-out with a 6mm margin versus 10mm margin of normal looking-skin?

Please TICK one box only:

| STRONG preference | SLIGHT preference | NO preference |
|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Initials:.....

DOB:.....

Participant code:.....

If you have ticked that you have a STRONG PREFERENCE for 1 of the treatments over the other, please state WHICH treatment you would prefer if you had a choice.

Preferred treatment:

Please outline the reasons why you have a strong preference for this treatment:

.....
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.....
.....

b) SCC cut-out and then receive extra radiotherapy to the area, or SCC cut-out with NO additional radiotherapy?

Please TICK one box only:

| STRONG preference | SLIGHT preference | NO preference |
|-------------------|-------------------|---------------|
| | | |

If you have ticked that you have a STRONG PREFERENCE for 1 of the treatments over the other, please state WHICH treatment you would prefer if you had a choice.

Preferred treatment:

Please outline the reasons why you have a strong preference for this treatment:

.....
.....
.....
.....

4 – From your own personal point of view, which of the following outcomes after treatment do you consider to be the most important (Tick one only)?

Good cosmetic appearance of the treated area

Getting rid of the cancer

Maintenance of function in the area

Decreasing the risk of the cancer coming back

Initials:.....

DOB:.....

Participant code:.....

Not working due to health.....

Student.....

Education level attained:

Postgraduate/professional qualifications

Graduate

'A' level

'O' level/GCSE

No formal qualifications

Initials:.....

DOB:.....

Participant code:.....

Focus Group

Would you be interested in taking part in a focus group with 4 or 5 other people to discuss in more detail issues relating to the proposed trial and other more general questions about taking part in clinical trials?

| | |
|----------------|--|
| Definitely YES | |
| Maybe | |
| NO | |

If you have answered 'yes' or 'maybe', a member of the research team will contact you with further details of the focus group.

Results Summary

Would you be interested in receiving a summary of the results of this research when we have analysed the data?

YES/NO

Helping in the future

Would you be interested in reviewing and commenting on information resources which we will be developing and will give to people who take part in our proposed trial, or to other patients who develop this type of skin cancer?

YES/NO

MANY THANKS FOR COMPLETING THIS QUESTIONNAIRE – YOUR RESPONSES ARE VERY VALUABLE TO US. PLEASE USE THE ENCLOSED PRE-PAID ENVELOPE TO RETURN YOUR COMPLETED QUESTIONNAIRE WITHIN 14 DAYS OF RECEIPT TO:

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