



# SINS Trial Results

The SINS trial evaluated two treatments for basal cell carcinoma - surgical removal and imiquimod cream. In total, 501 people with basal cell carcinoma took part in the trial - making it the largest trial of its kind. We've now finished analysing all the data and we are pleased to be able to share the results with you.

## What was the trial about?



Superficial basal  
cell carcinoma



Nodular basal  
cell carcinoma

Basal cell carcinoma is the commonest human cancer. It is usually found on the sun-exposed areas of skin in older people. It is a slow growing skin cancer which eventually causes an ulcer to form in the skin. These ulcers can bleed and become unsightly. It is extremely rare for the tumour to spread.

The SINS study compared local surgery (normally the best way of for treating people with such skin cancers) against imiquimod cream (5%), a skin treatment which stimulates the body's immune system to fight cancer.

Although imiquimod wasn't expected to be as successful as 'gold standard' treatment, it was important to find out exactly how good it was compared to surgical removal, and see if it had any other benefits (such as how the skin appeared afterwards).

## What did the trial involve?

Participants were placed in two groups at random, with an equal chance of being allocated to either group. Participants were either treated with imiquimod daily (for 6 weeks if the basal cell carcinoma was superficial, and 12 weeks if it was nodular) or simple surgery.

Information was collected by the research nurses at visits or by telephone call. At the visits, dermatologists checked whether the treatment worked, that the skin cancer hadn't come back

(recurred), and recorded any symptoms or other changes in health. At the later visits we also asked participants what they thought about the appearance of the treated area.

When the analysis was performed, this was done with the groups labelled as A and B, without knowing which treatment was which, so that the analysis was "blinded". This is to prevent any bias when decisions were made about the analysis.

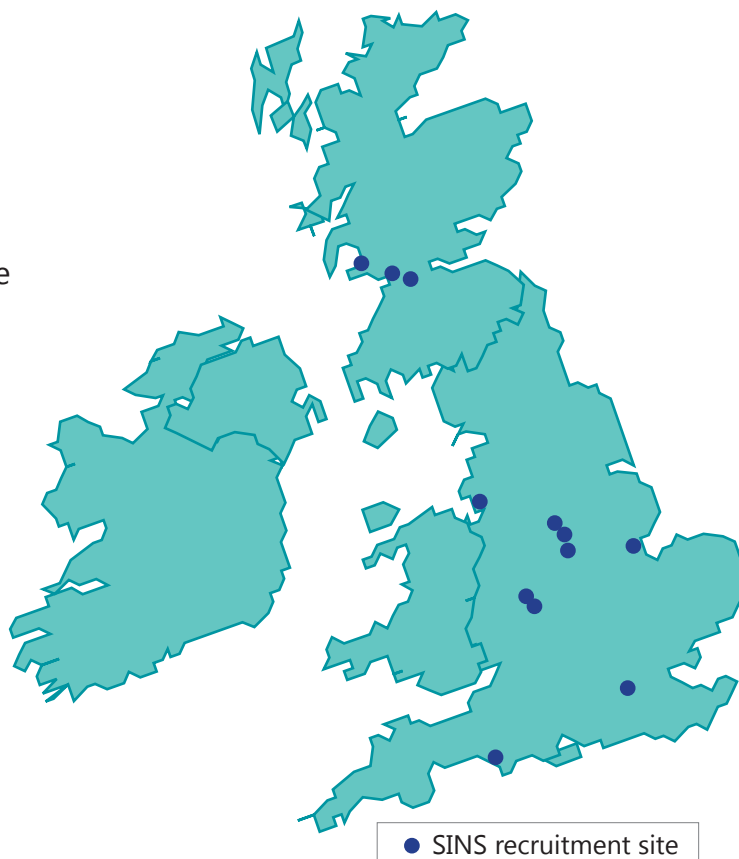
## Who took part in the trial?

Patients with a low-risk basal cell carcinoma were invited to take part in the SINS trial. In total, 501 people were enrolled from hospitals across England and Scotland.

The age of people in the trial ranged from those in their 30's to those in their 90's, but the average age was 68 years. There were slightly more men than women.

There was nearly an even split between participants who had superficial basal-cell carcinoma (51%) and participants who had nodular basal cell carcinoma (49%). The majority of participants (two-thirds) had not previously had a basal cell carcinoma.

Of the 501 participants, 254 were randomly assigned to the imiquimod group and 247 to the surgery group.



## What did patients think of the treatments?

We wanted to find out what patients with basal cell carcinoma think about having an alternative option to surgery, and what treatment outcomes are most important when deciding on a treatment.

We designed a questionnaire to help us find out whether certain aspects of treatment are important to patients. These aspects include types of side effects, changes in appearance and chance of cancer clearance.

We asked some of the participants in the SINS trial to complete the questionnaire before they received treatment. A total of 174 (95%) of participants completed the questionnaire.

The results showed that patients value all of the aspects we asked about, but are more likely to be worried about the cosmetic outcome and

side effects they might experience rather than the chance of clearance.

A cream option (with better cosmetic outcomes) was more appealing than surgery (with better clearance outcomes). However, participants who had a previous basal cell carcinoma removed by surgery were less likely to value the cream option.

These results will help healthcare professionals discuss the outcomes of different treatment options, as they will have a better understanding of those which are valued by patients. Additionally, the findings may better inform the development of health care treatment options.

## What were the results of the main study?

A treatment was considered to be successful when:

- it worked the first time it was used, and,
- There were no signs of local recurrence (meaning that the treated basal cell carcinoma did not reappear at the treatment site)

After three years we found that treatment was successful for:

**84% of participants in the imiquimod group**  
**98% of participants in the surgery group.**

This was for all patients with basal cell carcinoma. Similar results were found when looking at patients with superficial and nodular basal cell carcinoma types separately.

Most of the failures in the imiquimod group occurred in the first year during or soon after treatment has finished

There was no significant difference in cosmetic appearance rated by participants – with results of both treatments scored as either excellent or good. However, a dermatologist (using photographs) gave twice as many excellent/good ratings to those treated with imiquimod.

After 5 years, we also checked medical records to see if there were any additional basal cell carcinoma recurrences:

1 had occurred in the imiquimod group,  
1 had occurred in the surgery group.

There were no serious adverse events related to either of the treatments.

These longer term data suggest that the benefits of imiquimod cream persist. In other words, if the cream works in the first year, it is likely to last.

The SINS study has provided really useful information that will help doctors and patients choose the right treatment for them.

**For more further details about the results of the trial, and links to the publications, visit:**

[www.nottingham.ac.uk/dermatology](http://www.nottingham.ac.uk/dermatology)

## How this trial is changing practice

We have been working hard to ensure the results of the trial are seen by both doctors and patients around the world. We have published the main results of the study in 'The Lancet Oncology' and have been presenting the research at international medical conferences.

Prior to this study, imiquimod cream was not used routinely for basal cell carcinoma, and clinical opinion was divided regarding its potential usefulness for different types of basal cell carcinoma. Now, imiquimod has become a recognised treatment for superficial basal cell carcinomas, and is sometimes also used for nodular basal cell carcinoma. This means that patients and their doctors have more choices to select from, and a better evidence-base on which to make their decisions thanks to those who kindly took part in the study.

## Who conducted the trial?



Dr Fiona Bath-Hextall  
Trial Lead



Professor Hywel Williams  
Chief Investigator



Mara Ozolins  
Trial Manager

Gaps in the evidence base for treating basal cell carcinomas were identified in a Cochrane systematic review, led by Dr Fiona Bath-Hextall. To address some of these evidence gaps, Dr Fiona Bath-Hextall and Professor Hywel Williams applied for funding from Cancer Research UK to investigate Surgery vs Imiquimod for Nodular and Superficial basal cell carcinoma (the **SINS** trial)

In total, staff from 12 centres in England and Scotland, helped to recruit patients into the trial. This included members of the NIHR Clinical Research Network team.

*Full funding acknowledgments: Cancer Research UK ([www.cancerresearchuk.org](http://www.cancerresearchuk.org)) provided most of the study funding. Additional funding in the form of a small R&D grant was provided by Nottingham University Hospitals NHS Trust. MEDA (formerly 3M) donated the 5% imiquimod cream used in the trial free of charge.*

We would like to take this opportunity to say how grateful we are to everyone who participated in the SINS trial. Without the extra time you have given this study would not have been possible, and important questions about the best treatment for basal cell carcinoma would not have been answered.

*Thank you!*

**Further information about this research, as well as links to all the SINS trial publications, can be found on our website:**

**[www.nottingham.ac.uk/dermatology](http://www.nottingham.ac.uk/dermatology)**

