

# A randomised controlled trial of excisional surgery versus imiquimod 5% cream for nodular and superficial basal cell carcinoma

<b>Submission date</b> 31/03/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-treatment-for-basal-cell-skin-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

Ms Mara Ozolins

### Contact details

Centre of Evidence Based Dermatology  
King's Meadow Campus  
Lenton Lane  
Nottingham  
United Kingdom  
NG7 2NR

## Additional identifiers

### Clinical Trials Information System (CTIS)

2004-004506-24

### ClinicalTrials.gov (NCT)

NCT00066872

### Protocol serial number

1066

# Study information

## Scientific Title

A randomised controlled trial of the effectiveness of excisional surgery versus imiquimod 5% cream for long-term clinical success rate in patients with nodular and superficial basal cell carcinoma

## Acronym

SINS

## Study objectives

1. Can imiquimod 5% cream applied topically give an acceptable and clinically useful success rate (3 year clinical clearance) and acceptable side effect profile when compared with excision surgery for superficial and nodular basal cell carcinoma (BCC) at low risk sites?
2. Is imiquimod more cost effective than surgery for low-risk BCC?
3. Does imiquimod result in a more aesthetically acceptable result than conventional excision?
4. Do certain phenotypic features and gene polymorphisms predict tumour responsiveness to treatment?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Queen's Medical Centre, Nottingham (now Nottingham Research Ethics Committee 2), 15/11/2001, ref: LREC:DE090101

## Study design

Randomised interventional multicentre treatment trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Melanoma; Disease: Skin

## Interventions

Simple excisional surgery with a 4 mm margin versus imiquimod 5% cream (Aldara) applied once daily for 6 weeks for superficial BCC and 12 weeks for nodular BCC.

Follow Up Length: 36 months (60 months from records)

Study Entry: Single Randomisation only

Last patient recruited: 22/02/2007

## Intervention Type

Drug

**Phase**

Phase III

**Drug/device/biological/vaccine name(s)**

Imiquimod 5% cream

**Primary outcome(s)**

Clinical evidence of success (absence of any signs of local recurrence) at 3 years

**Key secondary outcome(s)**

1. Recurrence at 1, 2 and 5 years
2. Time to first recurrence
3. Aesthetic appearance of lesion site
4. Daily pain during and for 16 weeks post-treatment
5. Cost effectiveness

**Completion date**

23/04/2010

**Eligibility****Key inclusion criteria**

1. Primary nodular or superficial basal cell carcinoma located in low risk area
2. Access to telephone
3. Histologically proven BCC

Male or female participants of any age were recruited.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**Key exclusion criteria**

1. Genetic or nevroid conditions e.g., Gorlin's syndrome
2. Morphoeic (microinfiltrative) as diagnosed clinically
3. Allergy to any of the interventions
4. Involvement in a trial of another experimental intervention
5. Life threatening disease
6. Bleeding disorders
7. Unavailable for 3 years follow-up
8. Pregnant or breastfeeding

**Date of first enrolment**

19/06/2003

**Date of final enrolment**

22/02/2007

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Centre of Evidence Based Dermatology**

Nottingham

United Kingdom

NG7 2NR

## Sponsor information

**Organisation**

University of Nottingham (UK)

**ROR**

<https://ror.org/01ee9ar58>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Cancer Research UK (CRUK) (UK) (ref: C7484/A2869; C7484/A8991)

**Alternative Name(s)**

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	04/10/2012		Yes	No
<a href="#">Results article</a>	results	01/01/2014		Yes	No
<a href="#">Protocol article</a>	protocol	21/04/2010		Yes	No
<a href="#">Plain English results</a>				No	Yes