

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

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

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Contact details

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Additional identifiers

EudraCT/CTIS number

2004-004506-24

IRAS number

ClinicalTrials.gov number

NCT00066872

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

19/06/2003

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

Age group

Other

Sex

Both

Target number of participants

Planned sample size: 500; Actual sample size: 501

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

England

United Kingdom

Study participating centre

Centre of Evidence Based Dermatology

Nottingham

United Kingdom

NG7 2NR

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

University Park

Nottingham

England

United Kingdom

NG7 2RD

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Paul.Cartledge@Nottingham.ac.uk

Sponsor type

University/education

Website

<http://www.nottingham.ac.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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

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