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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	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2010	**Overall study status** Completed	
Last Edited 18/10/2018	**Condition category** Cancer	

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

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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 nevoid 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
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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?

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