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A trial comparing Metvix® photodynamic therapy followed by Mohs micrographic surgery against Mohs micrographic surgery alone for the treatment of basal cell carcinoma

Submission date 03/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/04/2006	**Overall study status** Completed	
Last Edited 16/05/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-004262-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A trial comparing Metvix® photodynamic therapy followed by Mohs micrographic surgery against Mohs micrographic surgery alone for the treatment of basal cell carcinoma

Study objectives
That using topical photodynamic therapy (PDT) prior to Mohs micrographic surgery (as an adjunct) in the treatment of basal cell carcinoma (BCC) will overall, reduce the post-Mohs wound defect size (mm^2) when compared to Mohs micrographic surgery alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by St Thomas' Hospital Research Ethics Committee on 06/12/2005, reference number: 05/Q0702/219

Study design
Single centre open randomised controlled pilot study with pre-entry concealment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Basal cell carcinoma (BCC)

Interventions
To assess whether the combination of PDT followed by Mohs micrographic surgery is superior to Mohs micrographic surgery alone in treating basal cell carcinoma in terms of reducing the post-Mohs wound defect and the mean number of stages required to achieve clearance

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. To measure and compare the post-Mohs wound defect surface area (mm^2) in the two groups
2. To compare the mean number of stages required to clear the lesion by Mohs' micrographic surgery in the two groups
3. To compare recurrence rates of BCC at 12 months post-operatively. The lesion response will be defined as one complete response (complete clearance) or zero incomplete response (incomplete clearance).

Secondary outcome measures
1. To assess whether there is any reduction in size (surface area, mm^2) of the lesion, clinically with PDT prior to Mohs (in the Metvix® PDT group) including assessment of fluorescence between the first and second sessions of PDT
2. Cosmetic outcome at months 3, 6 and 12 after the Mohs surgery

Overall study start date
06/02/2006

Completion date
01/10/2007

Eligibility

Key inclusion criteria
1. Male or female subjects older than 18 years
2. The above should have a basal cell carcinoma at least 100 mm^2 in surface area and appropriate for treatment with Mohs micrographic surgery
3. Female subject of non-childbearing potential
4. Subject must be willing and capable of cooperating with the study protocol
5. Subject has to be able to read the patient information sheet as well as read and sign the informed consent form prior to any procedure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria

1. BCCs with less than 100 mm^2 in surface area
2. Clinically or histologically morphoeic basal cell carcinoma
3. Female of child-bearing potential
4. Subject with a history of porphyria, xeroderma pigmentosa or other photosensitive skin condition
5. Subject with known hypersensitivity to methyl 5-aminolevulinate, a similar compound or excipients of the cream
6. Subject who is at risk in terms of precautions and contraindications in the package insert for Metvix®
7. Subject who has participated in another investigational drug or device research study within 30 days of enrolment
8. Subject with a condition or who is in a situation, which in the investigators opinion may put the subject at significant risk, may confound the study results or may interfere significantly with the subjects participation in the study. This includes individuals unable to understand the implications or procedures of the trial, for example if they cannot adequately understand written or spoken English.

Date of first enrolment
06/02/2006

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dermatological Surgery and Laser Unit
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
Guy's and St Thomas' NHS Foundation Trust (UK)

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?
Basic results			16/05/2019	No	No