

# Squamous cell carcinoma prevention in organ transplant recipients using topical treatments

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>10/07/2014   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>10/07/2014 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>28/05/2020       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/trials/a-study-looking-treatment-prevent-skin-cancer-people-who-have-had-organ-transplant-spot>

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Yolande Jefferson-Hulme

### Contact details

Cancer Research UK Clinical Trials Unit  
Institute of Cancer and Genomic Sciences  
University of Birmingham  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TT

-  
SPOT@trials.bham.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

2013-000893-32

### Protocol serial number

16962

# Study information

## Scientific Title

Squamous cell carcinoma prevention in organ transplant recipients using topical treatments: a feasibility study (SPOT)

## Acronym

SPOT Trial

## Study objectives

A multi-centre, randomised, three arm, open-label, phase II, feasibility study comparing topical treatment of actinic keratoses (AK) in Organ Transplant Recipients (OTR) using 5-fluorouracil or 5% imiquimod (plus sunscreen) to standard care (sunscreen alone) in the prevention of squamous cell carcinoma (cSCC). The main objective of this study is to establish the feasibility of performing a phase III randomised controlled trial evaluating prevention of cSCC using currently available topical interventions.

On 10/12/2014 the following changes were made to the trial record:

1. The overall trial start date was changed from 01/08/2014 to 01/12/2014.
2. The overall trial end date was changed from 01/08/2015 to 01/12/2016.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

13/LO/1579; First MREC approval date 17/02/2014

## Study design

Randomised; Interventional; Design type: Treatment

## Primary study design

Interventional

## Study type(s)

Treatment

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

Topic: Cancer, Dermatology; Subtopic: Melanoma, Skin (all Subtopics); Disease: Skin, Dermatology

## Interventions

1. 5% w/w 5-fluorouracil cream (Efudix®), with discretionary sunscreen as per standard care, for 4 weeks (Treatment Cycle 1), followed by a 4-week resting period and then another 4-week treatment phase (Treatment Cycle 2). Topical treatment will be applied to the chosen treatment zone(s) once or twice per day dependent on the site of the AK.;
2. 5% imiquimod cream (Aldara®), with discretionary sunscreen as per standard care, for 4 weeks (Treatment Cycle 1), followed by a 4-week resting period and then another 4-week treatment phase (Treatment Cycle 2). Topical treatment will be applied to the chosen treatment zone(s) overnight for 3 (Mon, Wed, Fri or Tue, Thu, Sat) to 5 times (Mon-Fri) per week dependent on the site of the AK.;

3. Standard care, discretionary sunscreen only (SPF >30), should be applied daily to all exposed areas of the skin at least 30 minutes before sun exposure and topped up as required, from April to October or during high-UVR exposure activities during winter months.

## **Intervention Type**

Drug

## **Phase**

Phase II

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

5% w/w 5-fluorouracil cream (Efudix®), 5% imiquimod cream (Aldara®)

## **Primary outcome(s)**

Proportion of patients who would be willing to use the treatment again; Timepoint(s): Month 15

## **Key secondary outcome(s)**

1. Assessment of QoL measure; Timepoint(s): Month 15
2. Clearance of AK; Timepoint(s): End of treatment periods (4 and 8 weeks post treatment)
3. Development of cSCC; Timepoint(s): 12 months post treatment
4. Evaluation of the proposed overall AK quantification scoring criteria; Timepoint(s): Established pre-trial
5. Measure concordance of AK diagnosis by clinicians; Timepoint(s): Month 15
6. Patient treatment preferences; Timepoint(s): Month 15
7. Persistence of clearance of AK; Timepoint(s): End of month 12
8. Proportion of eligible patients who complete treatment cycle 1; Timepoint(s): Week 4
9. Proportion of eligible patients who require & complete treatment cycle 2; Timepoint(s): Week 12
10. Proportion of eligible patients willing to be randomised; Timepoint(s): Randomisation

## **Completion date**

03/07/2018

# **Eligibility**

## **Key inclusion criteria**

1. Organ Transplant Recipient (OTR) Patient Group:
  - 1.1. OTRs aged >18 years
  - 1.2. A minimum of 10 AK (with at least 5 AK occurring within the same skin zone)
  - 1.3. Demonstrably stable renal function on the basis of serum creatinine and estimated Glomerular Filtration Rate (eGFR)
  - 1.4. No recent change in immunosuppressive medication and predicted to remain stable over course of the study
  - 1.5. Able to apply topical cream as directed to the required area or having a carer who agrees to do this at the required frequency and times
  - 1.6. Women of childbearing potential, or men in a relationship with a woman of childbearing potential, prepared to adopt adequate contraceptive measures if sexually active
  - 1.7. Able to give written informed consent
  - 1.8. Willing and able to comply with scheduled visits, treatment plan, laboratory tests and other

study procedures

2. Immunocompetent Patient Group (participating in the DCE substudy only):

2.1. ICP patients aged >18 years

2.1. Present or previous AK (any site, any number)

2.3. Able to give written informed consent

2.4. Willing to spend up at least 20 minutes completing the Long Q

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

101

### **Key exclusion criteria**

Organ Transplant Recipients (OTR) only:

1. Pregnant (female patients of child bearing potential should have a urine or blood Human Chorionic Gonadotropin

(hCG) test performed to rule out pregnancy prior to trial entry)

2. Lactating females. Patients who agree to discontinue nursing 14 days prior to commencing treatment and do not

nurse throughout all the treatment period are eligible

3. Life expectancy less than 12 months

4. Known hypersensitivity or intolerance to 5-fluorouracil, imiquimod, sunscreen, or to any of the excipients (including but

not limited to: methylhydroxybenzoate, propylhydroxybenzoate, cetyl alcohol, stearyl alcohol, polysorbate 60, propylene

glycol, methyl parahydroxybenzoate and white soft paraffin)

5. The use of brivudine, sorivudine and analogues is prohibited

### **Date of first enrolment**

01/12/2014

### **Date of final enrolment**

01/12/2016

## **Locations**

### **Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Cancer Research UK Clinical Trials Unit**  
School of Cancer Studies  
University of Birmingham  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TT

## **Sponsor information**

**Organisation**  
Queen Mary University of London (UK)

**ROR**  
<https://ror.org/026zzn846>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
MEDA Pharmaceuticals Ltd (UK)

**Funder Name**  
NIHR (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0110-21244

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not expected to be made available

## Study outputs

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a>        |         |              | 28/05/2020 | No             | No              |
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |