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Squamous cell carcinoma prevention in organ transplant recipients using topical treatments

Submission date	Recruitment status	[X] Prospectively registered
10/07/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/07/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/05/2020	Cancer	

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

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Additional identifiers

EudraCT/CTIS number
2013-000893-32

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 ll, 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

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

Secondary outcome measures
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

Overall study start date
01/12/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

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
England

United Kingdom

Study participating centre
Cancer Research UK Clinical Trials Unit
School of Cancer Studies
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Sponsor information

Organisation
Queen Mary University of London (UK)

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Sponsor type

University/education

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

Publication and dissemination plan
We intend to publish protocol, trial results and translational sub-study results.

Intention to publish date

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?
Basic results			28/05/2020	No	No
HRA research summary			28/06/2023	No	No