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Combined Local Immunotherapy and Radiotherapy in metastatic Melanoma

Submission date	Recruitment status	[X] Prospectively registered
17/09/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/11/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/12/2017	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Angus Dalgleish

Contact details
Cellular and Molecular Medicine
Level 2 Jenner Wing
St George's University London
Cranmer Terrace
London
United Kingdom
SW17 0RE
+44 (0)20 8725 0809
dalgleis@sgul.ac.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Combined Local Immunotherapy and Radiotherapy in metastatic Melanoma: an interventional single-arm trial

Acronym
CLIRM-1

Study objectives
Malignant melanoma lesions can be cleared using a combination of local immunotherapy (Toll-like receptor [TLR] agonists and interleukin-2 [IL-2]) and radiotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wandsworth Research Ethics Committee, approval pending as of 17/09/2009

Study design
Interventional single-arm single-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metastatic melanoma

Interventions
All participants will receive the following treatments:
1. Aldara® cream applied four times weekly. Each sachet of 250 mg is sufficient to cover 20 square centimeters, so amount of cream used depends on the size of the lesion.
2. Intralesional injections of Proleukin® and Hiltonol®:
2.1. Proleukin® will be diluted to a concentration of 10 micrograms interleukin-2 per millilitre (10 ugml). Each lesion will have 100 microlitre injections, up to three in number depending on the size of the lesion. This will be performed three times weekly.
2.2. Hiltonol® is a 2 mg/ml solution and again, 100 microlitre injections will be made intralesionally, with a maximum of three injections per lesion, three times weekly.
3. Local radiotherapy

The total duration will be one year if the treatment is effective, but we anticipate an average of 36 weeks, depending on the choice of radiotherapy schedule.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Imiquimod (Aldara®), aldesleukin (Proleukin®), poly-ICLC (Hiltonol®)

Primary outcome(s)
Size of lesion

All primary and secondary outcome measures will be measured formally at entry, after 1 month, 6 months and end of trial.

Key secondary outcome(s))
1. Toxicity associated with this treatment will be measured by the number of adverse and serious adverse events during treatment, and the number of injections delayed in case of excessive local reaction.
2. Frequency and latency of appearance of any new skin lesions local or distal to the treated area will be recorded
3. Levels of markers associated with tumour infiltrating lymphocytes and tumour associated macrophages will be estimated by real time polymerase chain reaction (RT-PCR) of material biopsied from the lesions
4. Systemic immune responses associated with this treatment will be assessed by analysis of serum levels of cytokines and white blood cell properties taken by blood sampling during treatment.

All primary and secondary outcome measures will be measured formally at entry, after 1 month, 6 months and end of trial.

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Both males and females, aged 16 to 85 years
2. Patients who have one or more malignant skin tumours confirmed histologically at diagnosis
3. Patients with malignant skin tumours for whom other standard therapy options are no longer appropriate or have been refused by the patient
4. Life expectancy of at least 3-6 months
5. Patients with a WHO performance status of 0, 1 or 2
6. Patients who are informed of and are willing and able to comply with the home application of the Aldara® cream
7. Patients who are willing and able to comply with the investigational nature of the study and who have signed a written informed consent form
8. Patients who are willing to receive the number of intra-lesional injections and biopsies required to complete the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with unstable or severe current medical conditions or active, uncontrolled infection
2. Patients with psychological or sociological conditions, addictive disorders or family problems which would preclude compliance with the protocol
3. Patients undergoing therapy at study entry with other investigational agents that are directly immunosuppressive
4. Patients having procreative potential who are not using adequate contraception
5. Patients with untreated/uncontrolled brain tumours
6. Patients with brain tumours which have been treated but which have not been stable for 3 or more months
7. Patients with known hypersensitivity to Hiltonol®, IL-2, Aldara®, cyclophosphamide (for patients 16 30) or any of the excipients
8. Any condition, which, in the opinion of the investigator might interfere with the safety of the patient or evaluation of the study objectives

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St George's University London
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's Healthcare NHS Trust (UK)

ROR
https://ror.org/039zedc16

Funder(s)

Funder type
Charity

Funder Name
Application to Cancer Vaccine Institute (UK) in progress as of 17/09/2009.

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes