

# Combined Local Immunotherapy and Radiotherapy in metastatic Melanoma

<b>Submission date</b> 17/09/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 12/12/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## 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 ug/ml). 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