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Sunitinib versus dacarbazine in the treatment of patients with metastatic uveal melanoma

Submission date 29/10/2010	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 29/10/2010	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 26/10/2022	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-possible-new-treatment-for-eye-cancer-uveal-melanoma-suave

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01551459

Clinical Trials Information System (CTIS)
2008-008794-55

Protocol serial number
8440

Study information

Scientific Title
A randomised Phase II study of sunitinib versus dacarbazine in the treatment of patients with metastatic uveal melanoma

Acronym
SUAVE

Study objectives
There is currently no effective systemic therapy for metastatic uveal melanoma.

Eligible patients will be randomised to one of two first line interventions: Dacarbazine or Sunitinib. Dacarbazine will be administered at a dose of 1000 mg/m^2 by IV on day 1, and repeated every 21 days until progression or unacceptable toxicity. 50 mg of sunitinib will be taken orally once a day for 28 days followed by 14 day break, until progression or unacceptable toxicity.

At baseline, target lesions will be identified by Chest/Abdo CT scan, (and Liver MRI if necessary). Patients will attend clinic every 3 weeks for medical assessments including collection of Adverse Events. Every 12 weeks from day 1 of study treatment (regardless of delays to clinic visits), patients will undergo medical imaging for tumour measurement (in accordance with Recist v1.1).

At identification of first progression of disease, it may be possible for the patient to crossover to the other study treatment (if they reach the cross-over eligibility criteria). For patients who cross over, they will continue with the visit schedule until identification of second progression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunderland Research Ethics Committee, 18/05/2010, ref: 10/H0904/15

Primary study design
Interventional

Study design
Multicentre randomised interventional treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Melanoma; Disease: Melanoma

Interventions
Control Arm (Dacarbazine): Dacarbazine 1000 mg/m^2 to be administered by IV on day 1, and repeated every 21 days until progression or unacceptable toxicity.
Experimental Arm (Sunitinib): Sunitinib 50 mg to be taken orally once a day for 28 days followed by 14 day break, until progression or unacceptable toxicity.

Study entry: single randomisation only

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Sunitinib, dacarbazine

Primary outcome(s)
Progression free survival - 12 weekly scans will pick up progression according to RECIST 1.1. Analysis of primary outcome will be performed once all patients have been followed up for at least 3 months (expected to be Jan 2013).

Key secondary outcome(s)
1. Overall survival will be measured from date of randomisation to the date of death from any cause. Patients still alive at the time of analysis are censored at the date of the most recent follow up.
2. Overall response rate is defined as the proportion of complete (CR) or partial responders (PR) as defined by the RECIST version 1.1
3. AEs recorded following randomisation will be classified according to CTCAE version 4.0
4. Time to progression on first-line treatment (TTP1) compared to time to progression on second-line treatment (TTP2) for patients who receive cross-over therapy
5. Overall response rate on first-line treatment (RR1) compared to overall response rate on second-line treatment (RR2) for patients who receive cross-over therapy

Initial analysis by Data Monitoring Committee is planned for April 2011. Interim analysis for futility will be conducted after 50% of the events have been observed.

Completion date
08/11/2012

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Patients with histologically or cytologically confirmed unresectable, metastatic uveal melanoma (histology must be available from a metastatic site)
2. Patients with disease that is not amenable to surgery, radiation, or combined modality therapy with curative intent
3. No prior systemic therapy for advanced disease, including regional delivery of drug therapy (prior surgery or radiofrequency ablation is acceptable)
4. Patients who have received prior radiotherapy are eligible, however, measurable lesions must not have been previously irradiated
5. Life expectancy greater than 12 weeks
6. Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2 (for ECOG scale of

performance)
7. At least one measurable target lesion, for further evaluation according to the Response Evaluation Criteria In Solid Tumours (RECIST) version 1.1
8. Aged greater than 18 years, either sex
9. Adequate haematological, renal and liver function as defined below and performed within 14 days of study inclusion:
9.1. Haemoglobin (Hb) greater than 10 g/dl, platelets greater than 100,000 mm3, white cell count (WCC) greater than 3.0 x 10^9/L, absolute neutrophil count (ANC) greater than 1.5 x 10^9 /L
9.2. Bilirubin less than 1.5 x ULN, Alkaline phosphatase less than 5 x ULN, transaminases less than 5 x ULN
9.3. Creatinine less than 1.5 x ULN
10. Able to provide written informed consent
11. Females of child-bearing potential who have a negative pregnancy test prior to study entry and be using adequate contraception, which they agree to continue for 12 months after the study treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Conjunctival melanoma
2. Received any previous systemic therapy for uveal melanoma
3. Known leptomeningeal or brain metastases
4. Patients with a history of prior malignant disease (only if they have had more than 3 years free of disease or have had adequately treated non-melanomatous skin cancer or in situ carcinoma of the cervix)
5. Had treatment with potent CYP3A4 inhibitors and inducers within 7 and 12 days respectively, prior to study treatment administration
6. Therapeutic anticoagulation for treatment of DVT/PE. Concomitant treatment with therapeutic doses of anticoagulants (low dose warfarin [Coumadin®] up to 2 mg PO daily for deep vein thrombosis prophylaxis is allowed).
7. Unstable systemic diseases including uncontrolled hypertension (greater than 150/100 mmHg despite optimal medical therapy) or active uncontrolled infections
8. Any of the following within the 6 months prior to study drug administration: myocardial infarction, severe/unstable angina, symptomatic congestive heart failure, cerebrovascular accident or transient ischaemic attack, or pulmonary embolism
9. Clinically significant abnormal cardiac function with abnormal 12-lead electrocardiogram (ECG). Ongoing cardiac dysrhythmias of National Cancer Institute Common Terminology Criteria

for Adverse Events (NCI CTCAE) grade more than or equal to grade 2, poorly controlled atrial fibrillation of any grade, or prolongation of the QTc interval to greater than 450 msec for males or greater than 470 msec for females.
10. Any other serious or uncontrolled illness which, in the opinion of the investigator, makes it undesirable for the patient to enter the trial
11. Any medical or psychiatric condition which would influence the ability to provide informed consent
12. Pregnant or lactating women
13. Lack of informed consent
14. Any previous investigational agent within the last 12 weeks

Date of first enrolment
04/10/2010

Date of final enrolment
08/11/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Liverpool Cancer Research Centre
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Sponsor information

Organisation
Clatterbridge Centre for Oncology NHS Foundation Trust (UK)

ROR
https://ror.org/05gcq4j10

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC) grant (ref: CRUK/09/017)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Pfizer UK

Alternative Name(s)
Pfizer Ltd, Pfizer Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Plain English results			26/10/2022	No	Yes