

ITEM - a phase II study of imatinib in the treatment of patients with metastatic uveal melanoma

Submission date 18/01/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 13/02/2008	Overall study status Completed	☐ 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-trial-looking-at-imatinib-for-melanoma-of-the-eye-that-has-spread>

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2007-006216-39

Protocol serial number

CCO2007/18

Study information

Scientific Title

A single arm, multi-centre, two stage, phase II study of imatinib in good performance status patients with c-kit positive metastatic melanoma

Acronym

ITEM

Study objectives

The aim of this study is to determine the efficacy of imatinib in patients with metastatic uveal melanoma based upon standard radiological and positron emission tomography (PET)/computed tomography (CT) response.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 06/02/2009: Bolton Research Ethics Committee gave approval on the 30th June 2008 (ref: 08/H1010/21)

Primary study design

Interventional

Study design

Single arm, multicentre, two stage, phase II study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Metastatic eye melanoma

Interventions

This is a single arm phase II study. Stored tissue of primary ocular tumour and/or metastatic biopsies will be collected at baseline to determine eligibility and will be available for associated translational research. All patients will be asked to consent for collection of serum samples at baseline. All patients will receive imatinib 400 mg to be taken by mouth once a day. Patients will be followed up every 28 days for toxicity and will remain on study drug until disease progression, death, unacceptable toxicity or patient choice. CT will be at baseline and at weeks 6 and 12 with 8 weekly scans thereafter. PET will be in selected centres at baseline, week 6 and 12. Patients will be followed until death for overall survival.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Imatinib

Primary outcome(s)

Progression-free survival at 3 months.

Key secondary outcome(s)

1. Objective response rate, according to Response Evaluation Criteria In Solid Tumours (RECIST) criteria, assessed every 8 weeks
2. Overall survival (OS) assessed at date of first treatment to date of death and safety and toxicity, assessed every 28 days
3. Biomarker correlation with outcome measures
4. PET response (European Organisation for Research and Treatment of Cancer [EORTC] guidelines, Young, 1999)

Completion date

01/04/2010

Eligibility

Key inclusion criteria

1. Patients with histologically or cytologically confirmed unresectable, metastatic uveal melanoma (c-kit positive on immunohistochemistry [IHC])
2. Any prior therapy for advanced disease excluding agents targeting c-kit
3. Life expectancy greater than 12 weeks
4. World Health Organization (WHO) performance status 0, 1 or 2
5. Presence of one or more measurable lesions
6. Age greater than 18 years, either sex
7. Adequate haematological, renal and liver function
8. Written informed consent provided by the patient

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Total final enrolment

25

Key exclusion criteria

1. C-kit negative uveal melanoma
2. Any previous investigational agent within the last 12 weeks

3. Known leptomeningeal or brain metastases
4. Any other serious or uncontrolled illness which, in the opinion of the investigator, makes it undesirable for the patient to enter the trial
5. Any medical or psychiatric condition which would influence the ability to provide informed consent
6. Pregnant or lactating women

Date of first enrolment

01/04/2008

Date of final enrolment

01/04/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Clatterbridge Centre for Oncology NHS Foundation Trust

Merseyside

United Kingdom

CH63 4JY

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) (ref: C1810/A9396)

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

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?
Plain English results			26/10/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes