

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

<b>Submission date</b> 18/01/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

### Contact name

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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)

## Study design

Single arm, multicentre, two stage, phase II study

## Primary study design

Interventional

## 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?
<a href="#">Plain English results</a>			26/10/2022	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes