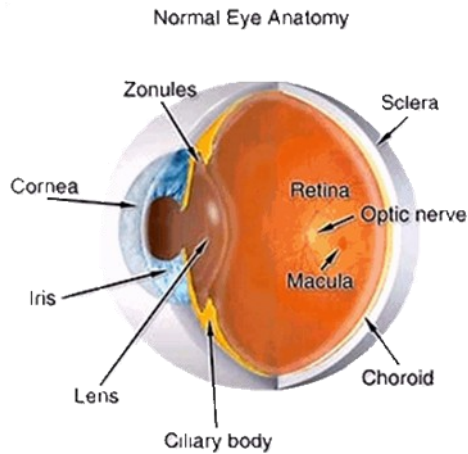


## Study Objective

A Phase II, UK based study of Imatinib in the treatment of patients with metastatic uveal melanoma. To evaluate the 3 month progression free rate of patients with unresectable good performance c-kit positive metastatic uveal melanoma treated with Imatinib.



## Outcomes

### Primary Outcome:

- Progression free survival at 3 months

### Secondary Outcomes:

- Safety and toxicity of Imatinib
- Progression free survival (overall)
- Overall survival
- Overall response rate (according to RECIST criteria)
- Biomarker correlation with outcome measures

## Background

- Uveal melanoma is the most common primary malignancy involving the eye, but remains rare
- Uveal melanoma is a separate disease distinct from cutaneous melanoma
- Approximately 5% of patients present with metastatic disease
- There is no effective systemic therapy for metastatic uveal melanoma
- A further 30-50% develop metastatic disease, usually within 3 years of primary treatment<sup>1</sup>
- The lack of activity noted to date using both chemotherapy and immunotherapy point to an urgent need to investigate novel therapies in this disease



## Inclusion Criteria

- Patients with histologically or cytologically confirmed unresectable, metastatic uveal melanoma
- Any prior therapy for advanced disease excluding agents targeting c-kit.
- Life expectancy > 12 weeks,
- Performance status 0, 1 or 2
- Presence of 1 or more measurable lesions, either clinically or radiologically, using RECIST criteria.
- Age > 18 years
- Adequate haematological, renal and liver function performed within 14 days of study inclusion
- Written informed consent provided by the patient
- Women of child-bearing potential must have a negative pregnancy test prior to study entry and be using adequate contraception, which must be continued for 12 months after the study
- Prior radiotherapy is allowed. However, measurable lesions must not have been previously irradiated.
- Patients must not have a history of other malignant disease other than adequately treated non-melanomatous skin cancer or in situ carcinoma of the cervix.

1. Sato T, Babazono A, Shields JA et al. Time to systemic metastases in patients with posterior uveal melanoma. *Cancer Invest* 1997;15:98-105.

## Trial Design

Single arm study for patients with unresectable good performance c-kit positive metastatic uveal melanoma. Two Stage Gehan trial design: In the event of 1, 2, 3, or  $\geq 4$  cases of progression-free survival among the first 14 patients after 3 months follow up, a further 1, 6, 9 or 11 patients, respectively, will be entered into the second stage

All patients will first consent to IHC testing on archived material of metastatic sites (all samples will be sent to Pathology Services, Royal Liverpool Hospital)

Patient secondary tumour assessed at pathology lab (for c-kit test) to determine eligibility. CT scan within 4 weeks of starting treatment.

Patient recruited to trial - 400mg IMATINIB per day. Baseline and Day 1 CRFs to be completed.

Patients to attend assessment 4 weekly and to collect 1 month supply of IMATINIB at visit. Week 6 CRF PET assessment for selected centres. CT scan at 12 weeks, then 8 weekly.

Second stage according to Gehan design (depending on progression free survival)

## The LCTU

The Liverpool Cancer Trials Unit works closely with **Cancer Research UK** in the clinical research of new and existing products for the treatment of cancer, easing suffering and improving the quality of life for cancer patients.

## Further Information

This trial is funded by Cancer Research UK, through FSC. The trial opened in August 2008

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For more information about Uveal Melanoma or current trials running within the **Liverpool Cancer**

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Or visit the LCTU website:

[www.lctu.org.uk](http://www.lctu.org.uk)

# LCTU

Liverpool Cancer Trials Unit

# ITEM



## A PHASE II STUDY OF

### *IMATINIB*

## IN THE TREATMENT OF PATIENTS WITH METASTATIC

## UVEAL MELANOMA