ISRCTN91548930 https://doi.org/10.1186/ISRCTN91548930

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/02/2008	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** Cancer	

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

Study website
http://www.lctu.org.uk/trial/ITEM.html

Contact information

Type(s)
Scientific

Contact name
Dr Ernist Marshall

Contact details
Clatterbridge Centre for Oncology NHS Foundation Trust
Clatterbrige Road
Bebington, Wirral
Merseyside
United Kingdom
CH63 4JY
+44 (0)151 482 7801
emarshall@nhs.net

Additional identifiers

EudraCT/CTIS number
2007-006216-39

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Progression-free survival at 3 months.

Secondary outcome measures
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)

Overall study start date
01/04/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
The trial will adopt a two-stage Gehan design enrolling 14 patients in the first stage, reaching a maximum of 25 patients

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
England

United Kingdom

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)

Sponsor details
Clatterbridge Road
Bebington, Wirral
Merseyside
England
United Kingdom
CH63 4JY
+44 (0)151 334 1155
Gill.Sims@ccotrust.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.ccotrust.nhs.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan

29/03/2018: Results presented at ASCO Annual Meeting 2012 (https://meetinglibrary.asco.org/record/70522/abstract)

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			26/10/2022	No	Yes