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Nilotinib in the treatment of c-KIT mutated advanced melanoma

Submission date 15/05/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/07/2009	**Overall study status** Completed	
Last Edited 27/09/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-nilotinib-treat-acral-mucosal-melanoma-skin-cancer-spread

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2009-012945-49

IRAS number

ClinicalTrials.gov number
NCT01395121

Secondary identifying numbers

ICR-CTSU/2009/10020

Study information

Scientific Title
A phase II trial of nilotinib in the treatment of c-KIT mutated advanced acral and mucosal melanoma (NICAM)

Acronym
NICAM

Study objectives
The NICAM trial will test the hypothesis that the c-KIT tyrosine kinase inhibitor nilotinib is active in c-KIT mutant advanced acral and mucosal melanoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire C, 20/11/2009, ref: 09/H0606/103

Study design
Single-arm phase II clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Advanced acral or mucosal melanoma

Interventions
Nilotinib 400 mg twice daily (bid). Treatment will continue for as long as the patient receives clinical benefit.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Nilotinib

Primary outcome measure
Proportion of patients progression free at 6 months

Secondary outcome measures
1. Response rate at 12 weeks
2. Overall survival at 6 months from treatment start
3. Toxicity of treatment at 6 months from treatment start
4. Correlation between c-KIT mutation, gene amplification, overexpression and response to treatment and survival at 6 months from treatment start
5. Changes in circulating tumour cells at 6 months from treatment start

Overall study start date
01/08/2009

Completion date
09/03/2017

Eligibility

Key inclusion criteria
1. Patients with c-KIT mutated histologically proven advanced mucosal or acral melanoma in which the mutation is not known to be associated with nilotinib resistance
2. Unresectable locally advanced or metastatic disease
3. The presence of one or more clinically or radiologically measurable lesions at least 10 mm in size
4. Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2
5. Life expectancy greater than 12 weeks
6. At least 28 days since major surgery and 7 days since skin/tumour biopsy
7. The capacity to understand the patient information sheet and the ability to provide written informed consent
8. Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests and other study procedures
9. Aged 18 years or greater, either sex
10. Women must be post-menopausal (no menstrual period for a minimum of 1 year) or have a negative serum pregnancy test on entry in the study (even if surgically sterilised). Men and women of childbearing potential must use adequate birth control measures (e.g. abstinence, oral contraceptives, intrauterine device, barrier method with spermicide, implantable or injectable contraceptives or surgical sterilisation) for the duration of the study and should continue such precautions for 6 months after receiving the last study treatment.
11. Serum alanine transaminase (ALT) less than or equal to 2.5 x upper limit of normal (ULN), total serum bilirubin less than or equal to 1.5 x ULN
12. Serum creatinine less than or equal to 1.5 x ULN

13. Haemoglobin greater than or equal to 9.0 g/dL, absolute neutrophil count greater than or equal to 1.5 x 10^9/L, platelets greater than or equal to 100 x 10^9/L
14. Prothrombin time (PT) less than or equal to 1.5 x ULN

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24 (Patients are first registered and progress to study entry if they remain eligible. Approximately 120 patients will be required to register to enable the target of 24 at study entry to be reached).

Total final enrolment
29

Key exclusion criteria
1. Intracranial disease, unless there has been radiological evidence of stable intracranial disease greater than 6 months. In the case of a solitary brain metastasis, evidence of a disease-free interval of at least 3 months post-surgery. All patients previously treated for brain metastases must be stable off corticosteroid therapy for at least 28 days.
2. Women who are pregnant, nursing, or planning to become pregnant during the course of the trial
3. Men who plan to father a child within 6 months of the last treatment
4. Use of any investigational drug within 30 days prior to screening
5. Significant cardiac disease including patients who have or who are at significant risk of developing prolongation of QTc
6. Severe and/or uncontrolled medical disease
7. Known chronic liver disease
8. Known human immunodeficiency virus (HIV) infection
9. Previous radiotherapy to 25% or more of the bone marrow
10. Radiation therapy in the 4 weeks prior to study entry
11. Prior exposure to a tyrosine kinase inhibitor

Date of first enrolment
15/12/2009

Date of final enrolment
04/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Marsden Hospital NHS Foundation Trust
London
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Sponsor information

Organisation
The Royal Marsden NHS Foundation Trust/The Institute of Cancer Research (ICR) (UK)

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Clinical R&D Office
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Sponsor type
Hospital/treatment centre

Website
http://www.icr.ac.uk/

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref: C28772/A11401)

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

Funder Name
Novartis (UK)

Alternative Name(s)
Novartis AG, Novartis International AG

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Publication and dissemination plan
A manuscript will be submitted to a quality peer-reviewed journal.

Intention to publish date
09/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from nicam-icrctsu@icr.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Basic results			No	No
HRA research summary		28/06/2023	No	No
Results article	16/02/2024	05/03/2024	Yes	No