# Adjunctive use of nilotinib in patient with imatinib resistant or intolerant chronic myeloid leukaemia (CML) undergoing a reduced intensity conditioned allogeneic transplant

Recruitment status	[X] Prospectively registered		
No longer recruiting	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed  Condition category	Results		
	Individual participant data		
Cancer	Record updated in last year		
	No longer recruiting  Overall study status  Completed  Condition category		

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

## Type(s)

Scientific

#### Contact name

**Prof Charles Craddock** 

#### Contact details

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## Additional identifiers

**Protocol serial number** RG\_07-202

# Study information

#### Scientific Title

Phase I/II study of the adjunctive use of nilotinib in patients undergoing reduced intensity allogeneic transplantation for imatinib resistant or intolerant chronic myeloid leukaemia

#### **Acronym**

**TRICE** 

## **Study objectives**

Disease relapse is the major cause of treatment failure after allogeneic transplantation using reduced intensity conditioned (RIC) regimens in patients with chronic myeloid leukaemia (CML) and therefore strategies which reduce the risk of disease relapse are required. Although there has been interest in the use of prophylactic donor lymphocyte infusions (DLI) to reduce the risk of relapse, their use is associated with a significant risk of severe graft-versus-host disease (GvHD) when administered early post-transplant. Nilotinib has potent anti-leukaemic activity in patients who are resistant or intolerant to imatinib and this study aims to examine whether its administration post-transplant can modify the kinetics of disease relapse after a RIC allograft thereby eliminating or postponing the requirement for DLI.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee, 24/10/2008, ref: 08/H0304/91

## Study design

Phase I/II multicentre single-arm open-label non-randomised study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Chronic myeloid leukaemia (CML)

#### Interventions

Nilotinib will be commenced on day +35 post-transplant. Nilotinib will be commenced at a dose of 200 mg daily (orally) for two weeks and if this is tolerated, it will be increased to 200 mg twice daily for a further two weeks. Patients will further escalate their dose to 400 mg twice daily (bd) until 12 months post-transplant. Nilotinib will then be discontinued. The total follow-up period is 13 months.

## **Intervention Type**

Drug

#### **Phase**

Phase I/II

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

#### **Nilotinib**

## Primary outcome(s)

Safety and tolerability of nilotinib therapy. Adverse events and therapy-related side effects will be monitored continuously during nilotinib treatment and until 28 days after the last dose.

## Key secondary outcome(s))

- 1. Relapse rate, assessed at 12 months post-transplant
- 2. Survival, assessed annually until 3 years post-transplant

#### Completion date

29/10/2010

# Eligibility

#### Key inclusion criteria

- 1. BCR/ABL positive CML in first chronic phase
- 2. Resistant or intolerant to imatinib mesylate
- 3. Aged greater than 18 years, either sex
- 4. Patients with a human leukocyte antigen (HLA) identical sibling donor or a suitable matched unrelated donor
- 5. Patients considered fit for transplantation
- 6. Patients must be able to swallow capsules
- 7. Liver function less than 2.5 upper limit of normal
- 8. In patients with magnesium and potassium levels below the lower limit of normal (LLN), every attempt should be made to normalise levels
- 9. All men and women of child bearing potential must agree to practice effective contraception during the entire study period
- 10. CML patients who have been treated with an investigational tyrosine kinase inhibitor who otherwise meet the definition or imatinib-resistance or intolerance are eligible
- 11. Give written informed consent prior to study specific screening procedures, with the understanding that the patient has the right to withdraw from the study at any time, without prejudice
- 12. Be willing and able to comply with the protocol for the duration of the study

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

All

## Key exclusion criteria

- 1. Patients with an allergy to fludarabine, busulphan, campath or nilotinib
- 2. BCR/ABL negative CML
- 3. Pregnant or lactating women
- 4. Patients with organ allografts
- 5. Impaired cardiac function
- 6. Patients with any other condition, which in the Investigator's opinion would not make the patient a good candidate for the clinical trial

#### Date of first enrolment

03/11/2008

## Date of final enrolment

29/10/2010

# **Locations**

#### Countries of recruitment

United Kingdom

England

## Study participating centre Queen Elizabeth Hospital

Birmingham United Kingdom B15 2TH

# Sponsor information

#### Organisation

University of Birmingham (UK)

#### **ROR**

https://ror.org/03angcq70

# Funder(s)

#### Funder type

Industry

#### **Funder Name**

#### Novartis Pharmaceuticals UK Limited

## Alternative Name(s)

Novartis UK, NOVARTIS UK LIMITED

## **Funding Body Type**

Private sector organisation

## Funding Body Subtype

For-profit companies (industry)

#### Location

**United Kingdom** 

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes