# Revlimid® Early Stage Poor prognosis Chronic lymphocytic leukaemia (CLL) Trial

Submission date Recruitment status [X] Prospectively registered 31/03/2010 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 31/03/2010 Completed [X] Results Individual participant data **Last Edited** Condition category 19/05/2022 Cancer

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

Mrs Helen Flight

#### Contact details

The Christie NHS Foundation Trust Wilmslow Road Manchester United Kingdom M20 4BX

# Additional identifiers

**EudraCT/CTIS number** 2009-011078-14

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers 7344

# Study information

#### Scientific Title

A single arm phase II study to investigate the use of Lenalidomide in the treatment of patients with early stage chronic lymphocytic leukaemia (CLL) associated with poor prognostic factors

#### Acronym

**RESPeCT** 

#### **Study objectives**

The majority of patients with chronic lymphocytic leukaemia (CLL) are diagnosed with early stage disease (Binet stage A or Rai stage 0/I). Standard management of such patients is observation, and with median age at diagnosis of 72 and median time to progression of greater than 5 - 10 years, many will never require treatment. In contrast, a proportion of patients have more aggressive disease, and over the last decade, a number of molecular factors have been identified that may be used to identify patients with poor prognosis disease. Each is associated with shortened time to treatment (typically less than 3 years in patients with two or more factors), reduced survival, with in the case of p53/ATM inactivation, resistance to treatment.

Whether it is possible to improve the outcome of patients with CLL and adverse prognostic factors by early intervention with treatment is unknown. Several trials in the 1980's demonstrated that treatment of stage A CLL with conventional chemotherapy (chlorambucil) did not alter the natural history of the disease, although none of these studies stratified patients according to risk. The choice of alternative potential therapeutic agents is limited; they should be effective in patients with adverse prognostic factors, have acceptable toxicity, be able to overcome the drug resistance associated with p53/ATM inactivation and ideally be orally administered.

Two recent phase II trials have demonstrated that Lenalidomide is effective in the treatment of relapsed/refractory disease. Importantly, both studies included a high proportion of patients with adverse prognostic factors including p53 inactivation. The principle objective of this study is to investigate the efficacy of Lenalidomide in achieving disease response (complete remission and clearance of minimal residual disease) in patients with poor risk early stage disease, together with assessment of safety and tolerability.

As of 02/05/2012, the anticipated end date of trial has been updated from 01/04/2012 to 24/11/2011.

#### Ethics approval required

Old ethics approval format

# Ethics approval(s)

North West 7 Research Ethics Committee approved on the 27th November 2009 (ref: 09/H1008 /122)

# Study design

Non-randomised multicentre interventional treatment trial

# Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

#### Study setting(s)

Other

#### 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

Topic: National Cancer Research Network; Subtopic: Haematological Oncology; Disease: Leukaemia (chronic)

#### **Interventions**

Oral lenalidomide at escalating dose for  $3 \times 28$  day cycles (2.5 mg daily, 5 mg daily, 10 mg daily), then maintenance phase at 10 mg (or maximum tolerated dose).

#### Intervention Type

Drug

#### Phase

Phase II

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

Lenalidomide

#### Primary outcome measure

Complete remission with clearance of minimal residual disease (MRD). Response to treatment to be assessed continually, with a more detailed assessment after 6 months of treatment (or earlier if clinically indicated). For patients in complete remission clearance of MRD is assessed every 6 months.

## Secondary outcome measures

- 1. Safety and tolerability of treatment, assessed continually throughout treatment by collection of adverse event data, blood results, etc.
- 2. Event free survival, assessed each time patients are seen at least once per month during treatment with study drug and then annually once off study drug and in long-term follow-up
- 3. Time to next treatment, assessed each time patients are seen at least once per month during treatment with study drug and then annually once off study drug and in long-term follow-up

## Overall study start date

01/04/2010

#### Completion date

24/11/2011

# **Eligibility**

#### Key inclusion criteria

- 1. Binet stage A CLL
- 2. Two or more risk factors:
- 2.1. Unmutated IgVH locus (=98% homology to germline sequence)
- 2.2. CD38 expression (greater than 7%)
- 2.3. Deletion of chromosome 11q22 (greater than 20% by FISH)
- 2.4. Deletion of chromosome 17p13 (greater than 10% by FISH)
- 3. Over 18 years old, either sex
- 4. Capable to provide written informed consent
- 5. Eastern Cooperative Oncology Group (ECOG) performance status less than 2
- 6. Life expectancy greater than 2 years
- 7. Must agree to not share study lenalidomide with someone else
- 8. Must agree not to donate blood whilst taking the study drug and for one week after discontinuation of treatment
- 9. Female subjects of child bearing potential and all male subjects must agree to comply with the stipulations of the pregnancy prevention plan

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

## Target number of participants

Planned Sample Size: 40; UK Sample Size: 40

#### Key exclusion criteria

- 1. Current or recent (within the last 1 month) participation in another clinical trial investigation the action of an investigational medicinal product for the treatment of CLL
- 2. Pregnant or lactating
- 3. Known positivity for human immunodeficiency virus (HIV) types 1 or 2
- 4. Prior history of malignancies, other than CLL, unless the subject was treated with curative intent and has been free of the disease for 3 years. Exceptions include the following:
- 4.1. Basal cell carcinoma of the skin
- 4.2. Squamous cell carcinoma of the skin
- 4.3. Carcinoma in situ of the cervix
- 4.4. Carcinoma in situ of the breast
- 5. Significantly abnormal renal or hepatic function:
- 5.1. Creatinine clearance less than 60 ml/min (measured or calculated)
- 5.2. Serum aspartate aminotransferase (AST) greater than 3 x upper limit of normal (ULN)
- 5.3. Serum bilirubin greater than 34 µmol/l
- 6. Laboratory tumour lysis syndrome according to the Cairo-Bishop classification. Subjects may be enrolled when these abnormalities have been corrected.
- 7. Peripheral neuropathy (grade = 2)
- 8. Previous treatment for CLL

- 9. Previous treatment with Thalidomide or immunomodulatory derivative drugs (including lenalidomide)
- 10. Treatment with corticosteroids (for CLL or other indications) less than 28 days from study entry
- 11. Evidence of Richter's transformation
- 12. Unsupported absolute neutrophil count less than 1 x 10^9/l or platelet count less than 50 x 10^9/l not due to CLL
- 13. Active autoimmune haemolytic anaemia or thrombocytopenia
- 14. Any other medical or psychological condition that in the view of the investigator would be likely to impact compliance with the protocol or interfere with trial treatment

#### Date of first enrolment

01/04/2010

#### Date of final enrolment

24/11/2011

# Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre The Christie NHS Foundation Trust

550 Wilmslow Road Manchester United Kingdom M20 4BX

# **Sponsor information**

# Organisation

Christie NHS Foundation Trust (UK)

#### Sponsor details

Wilmslow Road Manchester England United Kingdom M20 4BX

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.christie.nhs.uk/

#### **ROR**

https://ror.org/03v9efr22

# Funder(s)

### Funder type

Industry

#### **Funder Name**

Celgene International Sàrl (Switzerland)

#### **Funder Name**

Leukaemia Research Fund (LRF) (UK)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

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?
Basic results		04/03/2021	19/05/2022	No	No
HRA research summary			28/06/2023	No	No