PCR133

Patient Experience of Second-Line Treatment for Relapsed/Refractory Chronic Lymphocytic Leukaemia in UK Clinical Practice: Study Methodology

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OBJECTIVES

Primary objective

To understand the experience of patients with relapsed/refractory chronic lymphocytic leukaemia who receive venetoclax + rituximab (Ven+R) or continuous treatment with Bruton's tyrosine kinase inhibitors (BTKis) at prespecified timepoints within the treatment journey

Secondary objectives

1. To describe the characteristics of patients enrolling into the study (including but not limited to demographics, clinical characteristics, treatment history and comorbidities)
2. To describe the healthcare resource use associated with current treatment
3. To describe adverse events on current treatment

CONCLUSIONS

As of August 2023, 71 patients have been recruited; 26 had been prescribed a BTKi and 45 prescribed Ven+R.

This study will provide novel real-world evidence on the patient experience for R/R CLL patients treated with Ven+R or BTKi in second line

Utilizing rigorous mixed-methods approaches, this study will support the treatment decisions of healthcare professionals and patients with R/R CLL

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INTRODUCTION

- For healthcare professionals treating patients with relapsed/refractory chronic lymphocytic leukaemia (R/R CLL), it is important to understand the experience of patients when making treatment decisions
- Available treatments for R/R CLL include the combination therapy venetoclax + rituximab (Ven+R)[1,2] and Bruton's tyrosine kinase inhibitors (BTKis) such as ibrutinib or acalabrutinib[3,4]
- Regarding treatment duration, Ven+R is administered with a fixed treatment duration of 24 months, whilst BTKis are administered continuously until disease progression or unacceptable toxicity
- Established quality of life (QoL) assessments used in clinical trials report little detail around the patient's experience with treatment
- Whilst multiple clinical trials report treatment outcomes with targeted treatments (including Ven and BTKis) in patients with CLL[6-8], patient-centric data around real-world treatment-related experience and QoL remain sparse
- A recent conceptual model demonstrated the symptom burden in patients with CLL but did not address the patient experience and burden with different treatments[5]
- This study addresses this knowledge gap utilizing a unique mixed-methods approach to provide novel patient-centric data regarding the real-world treatment-related experience and QoL of patients with R/R CLL on second-line fixed-duration (Ven+R) or continuous treatments (ibrutinib and acalabrutinib; BTKis)

METHODS

- This is a non-interventional, cross-sectional, mixed-methods study (ClinicalTrials.gov #NCT05555979)
- The study gained ethical approval in October 2022 (London-Surrey Borders Research Ethics Committee)
- The study opened for data collection in November 2022 and will complete November 2023 (first results expected mid 2024)
- The study cohort comprises of eligible patients with R/R CLL receiving second-line treatment across 10 study centres (**Figure 1**)
- Pseudonymised study data is collected via qualitative interviews and retrospective chart review.
- Each treatment group (Ven+R/BTKis) will be further stratified into sub-cohorts defined by their stage/duration of treatment at their time of enrolment (**Figure 1**)
- Interviews are expected to last 60-90 minutes and will follow a semi-structured guide developed collaboratively with CLL support (patient-led UK Charity)
- Verbatim interview transcripts are coded using Atlas.ti software, with key interview and analysis themes outlined in **Figure 2**
- Retrospective chart review will be utilized to collect descriptive and clinical variables including:
  - demographics
  - clinical characteristics
  - response to current treatment if available (at enrolment)
  - treatment history
  - healthcare resource use
  - adverse events
- Study analysis will be descriptive in nature with no direct statistical comparisons made

Figure 1.

Patients will be recruited from 10 geographically disparate clinical centres across the UK

Inclusion Criteria:

- ≥18 years of age
- A confirmed diagnosis of CLL[9]
- The patient must have R/R disease,
- The must haved received only 1 prior line of treatment, which must have been a chemotherapy or chemoimmunotherapy treatment
- The patient must meet the criteria for inclusion in one of the cohorts (1 – 2c; see **Figure 2**)
- The patient must be able to provide informed consent, take part in the interview process, and complete all study procedures

Exclusion Criteria:

- Patients who were previously treated (at first line) with a BTKi, a BCL-2 inhibitor, or other targeted investigational agents
- Patients in cohort 2c must not have initiated their next line of treatment following disease[9] and treatment completion with Ven+R
- Has any other medical condition or disorder that could compromise a participant's ability to take part in the study

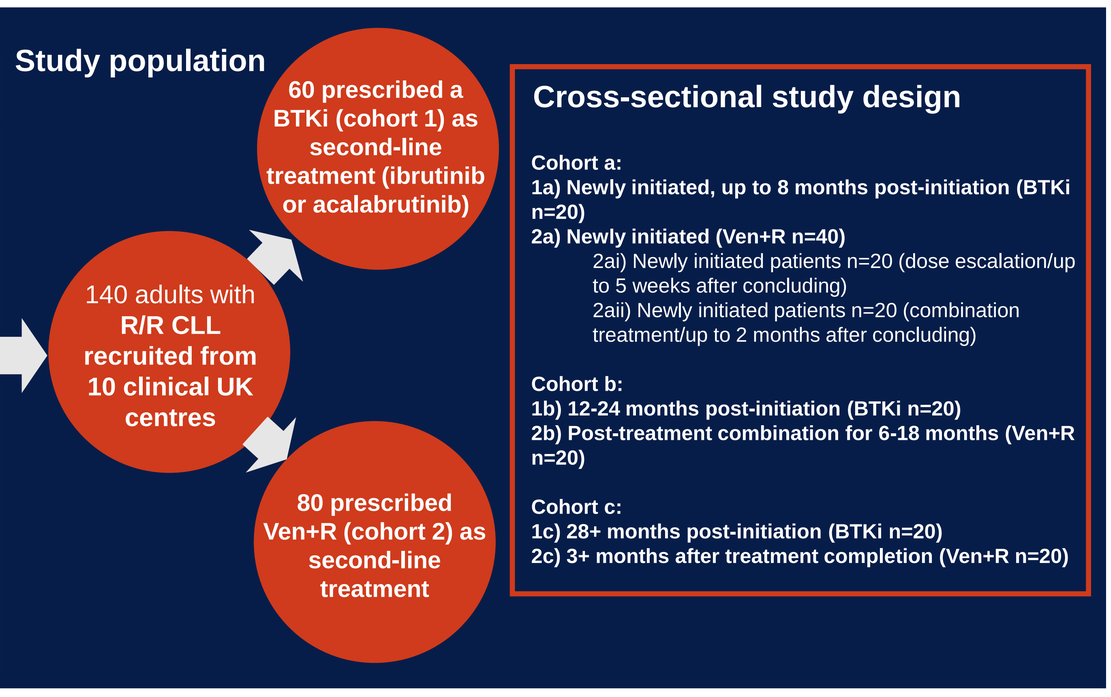

Figure 2. Key interview themes

Impact of treatment on the patient	Quality of life, controlling symptoms, ability to perform everyday tasks, attitudes and treatment effects throughout the treatment journey
The patient's experience starting treatment	Involvement in treatment decision, understanding of deep response, information explained to them prior to treatment initiation
Patient experience at prespecified timepoints	Capture treatment initiation, on/off treatment periods
Patient perspective of treatment duration	Patient perspective of the holistic value of a fixed duration treatment and how this differs to the holistic value of continuous treatment

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