

A QUALITATIVE STUDY TO EXPLORE THE PATIENT EXPERIENCE OF CONTINUOUS COVALENT BRUTON TYROSINE KINASE (BTK) INHIBITORS IN CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): STUDY METHODOLOGY

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Background: BTK inhibitors, including zanubrutinib, acalabrutinib and ibrutinib, are novel therapies which have greatly improved treatment outcomes for patients with CLL. While side effects of BTK inhibitors are documented in their respective clinical trials, there is limited data on the impact of these side effects on patient lives. Furthermore, the relevance and importance of these side effects may be assessed differently by clinicians and patients, impacting the clinician and patient experience. There is also limited research on the extent to which treatment-related side effects impact the lives of care partners, who support a patient's journey in CLL.

Aims: The aim of this study is to explore the experiences of patients, care partners and clinicians regarding side effects associated with the use of continuous covalent BTK inhibitors in CLL. The study will also examine the impact of side effects on the daily lives of individuals with CLL and the relative importance of different side effects to patients, care partners and clinicians. Exploratory objectives include assessing the similarities and differences in the patient experience with different covalent BTK inhibitors.

Methods: This is a non-interventional, qualitative interview study. Participants include individuals diagnosed with CLL currently taking a continuous covalent BTK inhibitor as a monotherapy for at least six months, care partners of such individuals, and clinicians with experience treating patients with CLL with continuous BTK inhibitors. Participants will be recruited across the UK, Germany, France, Italy and Spain and will be identified via a specialist recruitment agency; eligibility will be confirmed via a screening questionnaire. Participants will first complete an online background questionnaire followed by a 60-minute qualitative interview conducted via teleconference. Interviews will follow a semi-structured interview guide which will include open-ended questions to explore experiences of using continuous BTK inhibitors, including side effects and related impact on patients and care partners. Participants will also be asked about the most and least impactful side effects.

The target sample for this study is 60 patients, 15 care partners, and 15 clinicians. The best practice in qualitative research is to keep collecting data until data saturation is reached (the point at which no new insights are obtained from conducting further interviews). The data collected during interviews will be analyzed using a combination of content and thematic analyses. This study was reviewed and approved by the WIRB-Copernicus Group (WCG) Independent Review board (IRB; tracking number: 20244460).

Results: The results of this study will summarize concepts relating to covalent BTK inhibitor side effects, related impact on patients and care partners, and the relative importance of different side effects to patients, clinicians and care partners. Descriptions will be illustrated with participant quotes.

Summary/Conclusion: Qualitative research can provide rich insight into the patient, care partner and clinician experience. This study will provide valuable insights into the patient experience of side effects associated with covalent BTK inhibitors, and potentially identify discrepancies between how these side effects are viewed by patient and clinicians. Ultimately, these findings will empower patients to know what to expect from their treatment and facilitate shared decision-making between patients and clinicians on the best treatment options.