Cancer Research Consortium of West Michigan
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FAST FACTS

URCC 24060: "IMPACT OF TARGETED THERAPY ON CANCER-RELATED COGNITIVE IMPAIRMENT"

PARTICIPANT ELIGIBILITY

1.1 Inclusion Criteria: TKI recipients

1.1.1 Participants must have a diagnosis of CML or CLL/SLL (i.e., Small Lymphocytic Lymphoma).

1.1.2 Participants must be scheduled to initiate TKI therapy for CML or CLL within 45 days or have initiated TKI therapy for CML or CLL within the previous 45 days.

- Note: For this protocol, eligible therapies include (but are not limited to) TKI/BTKI agents (e.g., acalabrutinib, bosutinib, dasatinib, ibrutinib, imatinib, nilotinib, pirtobrutinib, ponatibib, zanabrutinib) as well as targeted therapies often used in combination with TKI/BTKI agents (e.g., asciminib, venetoclax). Any of these additional targeted therapy agents commonly used in treatment of CML/CLL can be used in combination therapy or monotherapy.
- Note: Changes in TKI therapy, such as switching or adding TKI agents, during the enrollment window do not affect eligibility.

1.1.3 Participants must be ≥ 18 years of age.

1.1.4 Participants must be able to speak and read English.

1.1.5 Participants must be able to understand and willing to sign an informed consent document.

1.2 Inclusion Criteria: Cancer-Free Individuals Serving as Controls

1.2.3 Participants must be ≥ 18 years of age.

1.2.4 Participants must be able to speak and read English.

1.2.5 Participants must be able to understand and willing to sign an informed consent document.

1.2.6 Each participant must be matched to a TKI recipient participant based on sex and age ±5 years (i.e., must be no more than 5 years older or younger than the TKI recipient participant).

1.3 Exclusion Criteria

1.3.3 Participants must have no history of metastatic cancer, primary brain tumor, or

brain irradiation.

1.3.4 Participants must have no more than 60 days of cumulative history of prior TKI therapy.

1.3.5 Participants must have no history of systemic cytotoxic chemotherapy, immune checkpoint inhibitor therapy, hormonal therapy, biologic therapy, or radiotherapy for cancer within the past 5 years. However, permitted treatments include prior use of hydroxyurea for the treatment of CML or CLL as well as treatment with obinutuzumab or rituximab concurrent with TKI therapy for CLL.

1.3.6 Participants must have no history of stroke within the past year and no remaining cognitive symptoms from any stroke prior to the past year.

1.3.7 Participants must have no history of head trauma with loss of consciousness within the year prior to consent.

1.3.8 Participants must have no diagnosis of dementia or severe neurodegenerative disease impairing daily functioning.

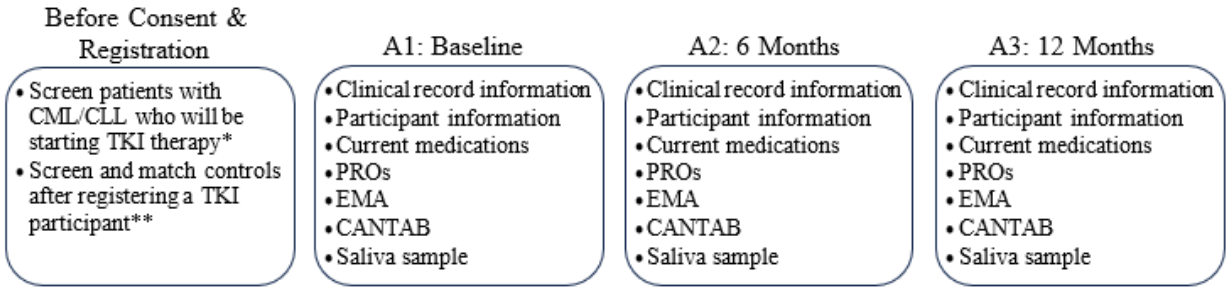
1.3.9 Participants must have no psychiatric condition that led to hospitalization within the past year.

1.3.10 Participants must not be currently pregnant.

1.3.11 Participants must not be colorblind based on self-report.

1.3.12 Participants must not be study staff who have previously viewed or administered the objective cognitive function measures (e.g., CANTAB).

2.0 STUDY SCHEMA



*TKI patients must be registered within 45 days before or after starting TKI therapy

**Controls must be matched based on sex and age ±5 years and registered within 90 days of completing the baseline assessment for the matched TKI participant