



European Society for Blood and Marrow Transplantation

Effect of 2nd generation TKIs prior to allogeneic SCT in CML

A non-interventional prospective study by the MPN subcommittee of the CMWP

Background

Stem cell transplantation will continue to be a treatment option for patients with chronic myeloid leukaemia, despite the introduction of tyrosine kinase inhibitors. However, many patients will have received prior therapy with TKIs, including Nilotinib or Dasatinib, at the time of allogeneic stem cell transplantation.

Although the use of Imatinib prior to stem cell transplantation seems to have no adverse impact on the outcome of allogeneic stem cell transplantation, little is known on the impact of prior use of second generation TK inhibitors.

This Non-Interventional Prospective Study addresses this question.

Patients undergoing allogeneic stem cell transplantation after prior use of 2nd generation TKIs will be followed by the EBMT Leiden office on engraftment, treatment-related mortality, relapse rate and survival, prospectively. Details on TKI therapy will be collected by the participating centres, retrospectively.

Objectives

- To evaluate the influence of prior treatment with second generation Tyrosine Kinase Inhibitors (TKIs) in CML patients on engraftment rates and treatment-related mortality during and after treatment with allogeneic HSCT.
- To evaluate the effect of prior second generation TKIs on treatment-related toxicity after treatment with allogeneic HSCT (i.e. incidence and severity of acute and chronic GVHD, SOS (VOD) of the liver, pulmonary complications, and causes of treatment-related mortality).
- To evaluate overall and disease-free survival.
- To evaluate the relapse rate.

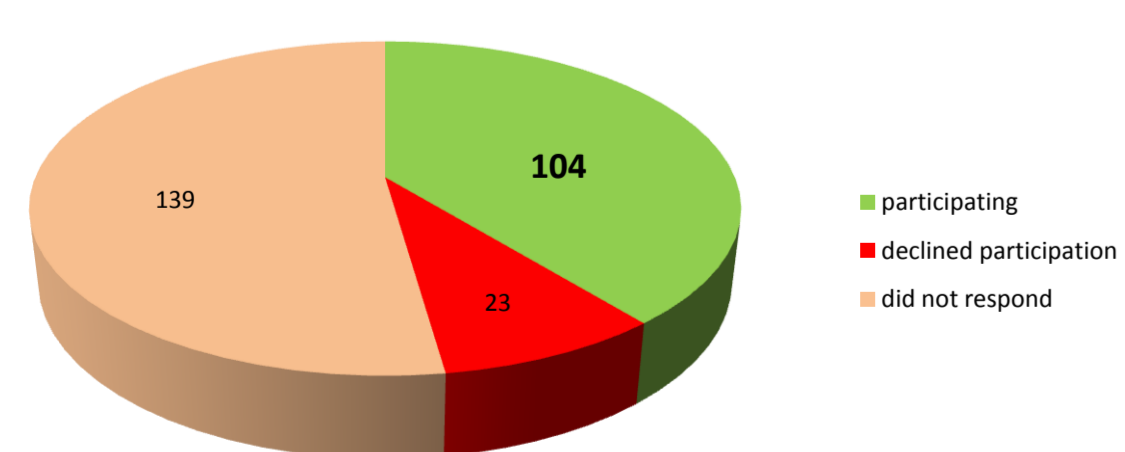
Inclusion Criteria

- CML
- >= 18 years old at time of transplant
- allogeneic stem cell transplant
- previously treated with Nilotinib and / or Dasatinib

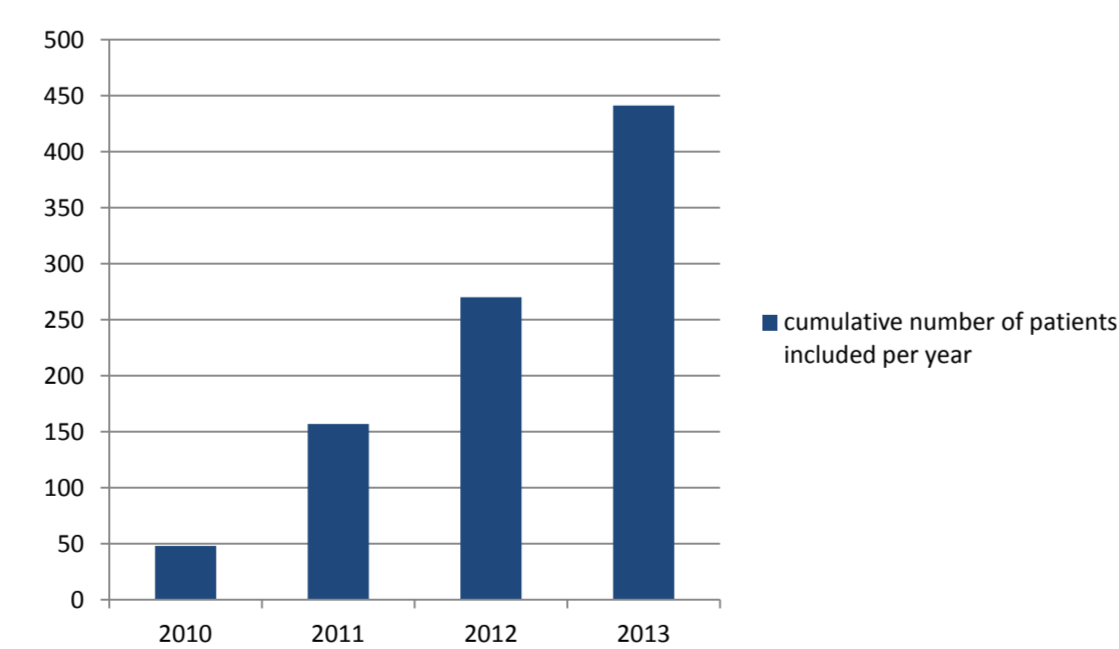
Participation

Study period: January 2010 - September 2013 with two years follow up

104 centres participating
(266 centres with CML patients invited)



443 patients included



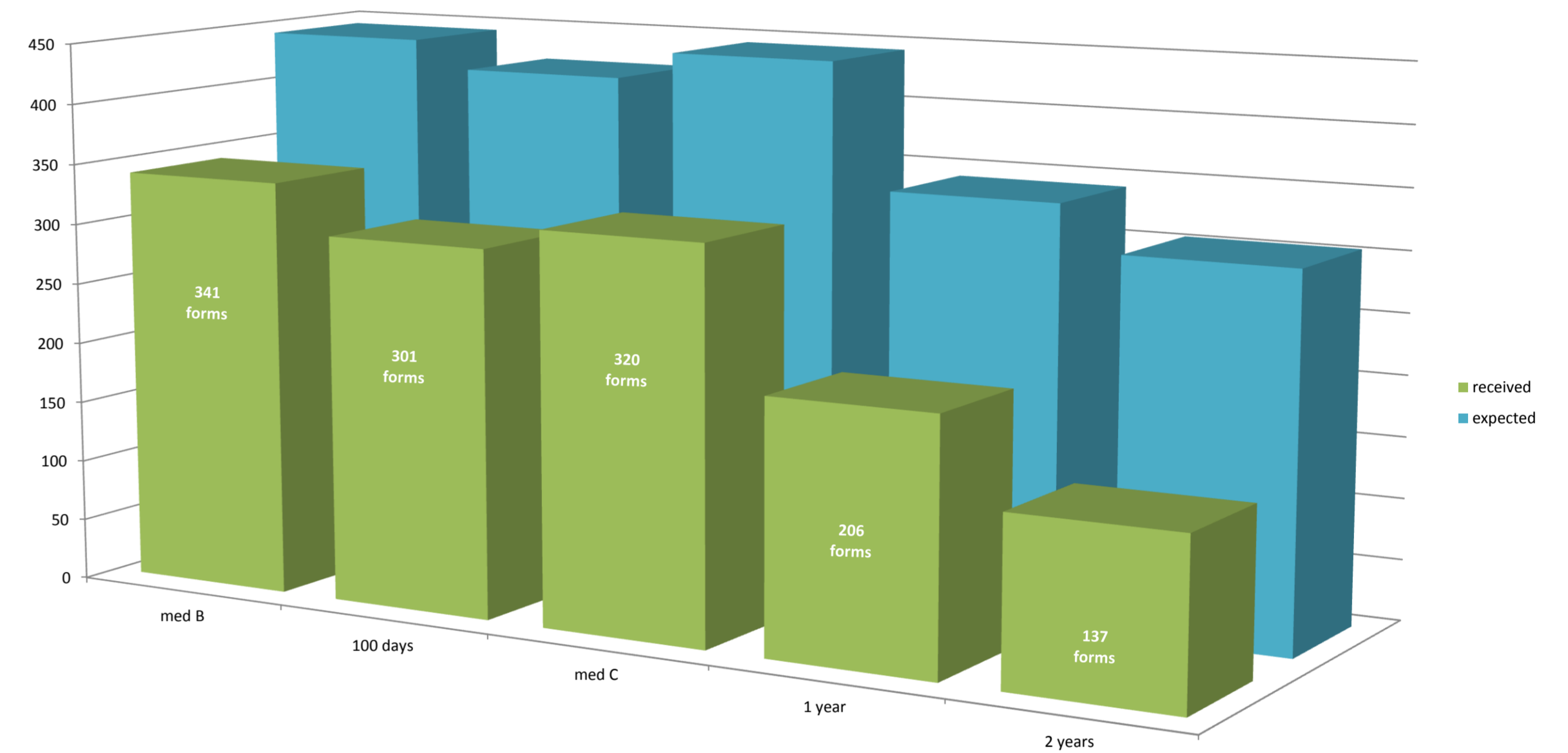
Centres per country



Data

Data collection is ongoing

- ❖ MED B form: 77% completed
- ❖ Day+100 form: 72% completed
- ❖ MED C form: 72% completed
- ❖ 1 year follow up form: 60% completed
- ❖ 2 year follow up form: 45% completed



Complete data expected and received

As the study is nearing the end of the follow-up period we are concentrating on collecting the last data and verifying any unclear entries. To this end we have created the TKI Data Quality Excel File, which marks all missing or ambiguous data with an orange outlined field. Participating centres have been sent this file for their patients in week 7, 2015.

We would appreciate completion of this file at your earliest convenience.

| X | Y | Z | AA | AB | AC | AD | AE |
|--------------------------|------------------------------------|---|------------------|----------------------|------------|-----------------------|----------------------------|
| TKPHIMRESP | TKRESPEC | IKSTATI | IKSTATNUMBI | IKTRANS | IKICR | TKPREVBLA | TKPREV |
| Response to Imatinib | | Status at 2nd generation TKI (dasatinib or nilotinib) | | | | | |
| Response to Imatinib | Specify other response to imatinib | status of disease at start 2nd generation TKI | Number of status | Translocation (9;22) | bcr-abl | Previous blast crisis | Previous accelerated phase |
| progression[7] | | accelerated phase[3] | first[1] | Present[2] | Present[2] | no[1] | yes[2] |
| No change/no response[6] | | chronic phase[1] | first[1] | Present[2] | Present[2] | no[1] | yes[2] |
| progression[7] | | | | | | no[1] | yes[2] |
| progression[7] | | blast crisis[2] | first[1] | Present[2] | Present[2] | yes[2] | no[1] |
| CHR[1] | | blast crisis[2] | first[1] | Present[2] | Present[2] | yes[2] | yes[2] |
| CHR[1] | | chronic phase[1] | first[1] | Present[2] | Present[2] | no[1] | no[1] |
| progression[7] | | | | | | yes[2] | no[1] |
| progression[7] | | blast crisis[2] | first[1] | Present[2] | Present[2] | yes[2] | no[1] |
| No change/no response[6] | | | | | | no[1] | yes[2] |

Contact

For study forms and information regarding the submission of data for this study, please contact the CMWP Data Office in The Netherlands:

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