PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

German MPN-Registry for BCR-ABL1-Negative Myeloid Neoplasms of the German Study Group MPN (GSG-MPN)

Trial Acronym

GSG-MPN-Registry

URL of the trial

https://www.cto-im3.de/gsgmpn/

Brief Summary in Lay Language

Myeloproliferative neoplasms (MPN) represent a very heterogeneous group of chronic hematologic diseases. Close collaboration and scientific exchange between the study centers is essential, due both to the rareness of the disease subtypes and the abundance of recent innovations in the field. The registry focuses on patient-centered care and the quality of life of patients with MPN. Due to its non-interventional character, it allows to include all patients with MPN, even those that may fail inclusion criteria of other clinical trials (i.e. due to significant comorbidities). The registry ensures a close collaboration between the participating centers, and furthermore, it aims at fostering evidence-based medicine by providing a network of physicians experienced in MPN diagnosis and therapy. At the beginning of this year, the fusion of both huge german MPN study groups (MPN-SAL and MPNSG) to the German Study Group MPN (GSG-MPN) was performed. Basis for this study group is this common MPN registry. Both registry protocols were adjusted accordingly (names, contents).

Brief Summary in Scientific Language

The GSG-MPN-Registry is a non-interventional prospective study with longitudinal patient recruitment (different time points for patients to enter the registry). All patients who meet the WHO criteria for BCR-ABL1-negative MPN, who are at least 18 years of age, and have given written informed consent can be included. Explicitly, patients with comorbidities who are not able to participate in an interventional study should be included into the registry.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006035**
- Date of Registration in DRKS: **2014/03/31**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **127/12 Aachen und 100/13 Ulm , Federführende Ethikkommissionen der Universitäten in Aachen und Ulm**

Secondary IDs

Health condition or Problem studied

- Free text: **Myeloproliferatiev disorders:**
  - Polycythemia vera
  - Primary and secondary myelofibrosis
  - Essential Thrombocythemia
  - Chronic eosinophilic leukemia
  - Hypereosinophilic syndrome
  - Systemic Mastocytosis
  - Chronic neutrophilic leukemia
  - Myeloproliferative disorder with eosinophilia and PDGFR-alpha-, PDGFR-beta- or FGFR1-Abberation
  - Unclassified myeloproliferative disorder
  - MDS/MPN-overlap syndromes
- ICD10: **D45 - Polycythaemia vera**
- ICD10: **D47.3 - Essential (haemorrhagic) thrombocythaemia**
- ICD10: **D47.4 - Osteomyelofibrosis**
- ICD10: **D47.0 - Histiocytic and mast cell tumours of uncertain and unknown behaviour**
- ICD10: **D47.1 - Chronic myeloproliferative disease**
- ICD10: **D47.5 - Chronic eosinophilic leukaemia [hypereosinophilic syndrome]**

Interventions/Observational Groups

- Arm 1: **In this observational study patients with MPN will be explored by assessing and evaluating their epidemiological and clinical data (symptoms, laboratory diagnostic). Additionally the quality of life will be assessed using a valid questionnaire (MPN-SAF).**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- Morphological and genetic diagnostics i.a. at date of diagnosis and during therapy
- Asservation of bone marrow and peripheral blood, plasma, and germline material
- Assessment of epidemiological data: age, prognostic factors, distribution of subgroups. Incidence and distribution of age are compared to the population based cancer registry.
- Assessment of the most important clinical outcomes: overall survival (OS), quality of life via questionnaire (MPN-SAF).

Secondary Outcome

- Assessment of further clinical outcomes: overall response rate (ORR), death-related morbidity (DRM), transfromation rate (TR).
- Assessment and evaluation of the quality of therapy and diagnosis via quality indicators.
- Validation of published prognostic factors and the search for possible new prognostic factors.
- Correlation of clinical endpoints with the chosen therapy regime.
- Assemement and description of new therapy regimes and new supportive care.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Zentren der German Study Group MPN (GSG-MPN) und weitere interessierte Institutionen, [---]***

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/09/02**
- Target Sample Size: **[---]***
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Diagnosis of a BCR-ABL1-negative MPN referring to WHO criteria and MPN with PDGFR-alpha-, PDGFR-beta-, or FGFR1-Aberration
- 18 years or older
- Written informed consent

Exclusion criteria

- < 18 years of age
- BCR-ABL1-positive chronic myeloid leukemia

Addresses

- **Primary Sponsor**

  Klinik für Hämatologie, Onkologie, Hämostaseologie und SZT, Uniklinik RWTH Aachen
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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

Klinik für Hämatologie, Onkologie und Stammzelltransplantation
Pauwelsstrasse 30
52074 Aachen
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Telephone: **[---]***

Institutional budget, no external funding (budget of sponsor/PI)

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- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Roonstrasse 25
90429 Nürnberg
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

* *This entry means the parameter is not applicable or has not been set.*

*** *This entry means that data is not displayed due to insufficient data privacy clearing.*