Luzerner Kantonsspital
Abteilung Hämatologie
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Geschäftsantwortsendung Invio commerciale-risposta
Envoi commercial-réponse

Nicht frankieren
Ne pas affranchir
Non affrancare

Key points

Design of the SLIM-Registry

The Registry is an online application with electronic case report forms. After successful registration data will be entered into prespecified entry masks.

Data entry

Data entry into the SLIM-Registry requires between 30 and 45 minutes per patient.

Administrative support

Submission of documents to your cantonal ethics committee (EC) for opening a site or for site expansion in case of an existing approval will be supported by the sponsor, Clinical Trial Unit (CTU) Haematology at Luzerner Kantonsspital. All documents needed for filing will be compiled for you and provided by post.

Costs

Costs of your cantonal EC will be covered by the sponsor, CTU Haematology at Luzerner Kantonsspital. For every patient documented completely you will receive CHF 300.– (CHF 200.– at registration, CHF 100.– at last Follow up).

Contact

In case of any questions please contact the investigators of the SLIM-Registry, Dr. Axel Rüfer at Luzerner Kantonsspital and Dr. Jeroen Goede at University Hospital Zürich, via email: axel.ruefer@luks.ch or Jeroen.Goede@usz.ch.

If you are interested in including patients into the SLIM-Registry please fill in the reply card and either fax or post it to the given address.

Swiss Lenalidomide In MDS del(5q) – Registry (SLIM-Registry)

Lenalidomide for patients with MDS del(5q) in daily practice in Switzerland – a data collection

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Swiss Lenalidomide In MDS del(5q) – Registry (SLIM-Registry)

Lenalidomide for patients with MDS del(5q) in daily practice in Switzerland – a data collection

Background

Myelodysplastic syndromes (MDS) constitute a heterogeneous group of clonal hematopoietic disorders characterized by bone marrow failure, persistent peripheral blood cytopenias and an increased risk of acute myeloid leukemia. Approximately 15 % of patients with MDS have a deletion of parts of the long arm of chromosome 5. Although many of those patients with MDS del(5q) have a relatively favorable prognosis, almost all patients will become transfusion dependent and experience a reduced life expectancy. A phase II[1] and a phase III study[2] evaluated the efficacy and safety of Lenalidomide treatment for achieving hematopoietic improvement in red blood cell transfusion dependent patients with low or intermediate-1 risk MDS with del(5q).

Lenalidomide was approved by Swissmedic in 2011 and is indicated for the treatment of patients with transfusion dependent anaemia resulting from MDS with low or intermediate-1 risk associated with del(5q) with or without additional cytogenetic abnormalities[3]. Lenalidomide was used in Switzerland for that indication since 2007 on a named patient basis.

Goals of the SLIM-Registry

This is a retrospective, non-interventional, multicenter data collection on the use, safety and efficacy of Lenalidomide in MDS-patients with del(5q) with or without additional cytogenetic abnormalities in daily practice in Switzerland. Data will be documented with regard to baseline characteristics of Lenalidomide-treated MDS-patients with del(5q), disease characteristics, treatment course and duration for each completed cycle of Lenalidomide, transfusion dependency and adverse events. There will be an annual Follow up after permanent discontinuation of Lenalidomide to collect survival data. Patients can be included into the Registry regardless of whether treatment with Lenalidomide is presently ongoing or was given in the past and regardless of whether treatment was given in hospital or in private practice to reflect daily practice of Haematologists and Haemato-Oncologists in Switzerland.

Inclusion criteria

- Male or female patients age ≥ 18 years
- Diagnosis of MDS
- Confirmation of del(5q) with or without additional cytogenetic abnormalities
- Previous or ongoing treatment with Lenalidomide
- Written informed consent only in patients who are alive.

No patient will undergo any additional investigations.

Exclusion criteria

Patients with MDS and no confirmation of del(5q).

References

1. List A, Dewald G, Bennett J, et al. Lenalidomide in the myelodysplastic syndrome with chromosome 5q deletion. N Engl J Med 2006; 355: 1456–65.
2. Fenaux P, Giagounidis A, Selleslag D, et al. A randomized phase 3 study of lenalidomide versus placebo in RBC transfusion-dependent patients with Low-/Intermediate-1-risk myelodysplastic syndromes with del5q. Blood 2011; 118: 3765–76.
3. Lenalidomid (REVLIMID®) Fachinformation

☐ **Yes, I would like to include patients in the Swiss Lenalidomide In MDS del(5q) – Registry (SLIM-Registry)**

My contact details are:

Title

Surname Name

Address

Zip Code, City

Telephone Fax

Email

Signature

Please send this card to fax 041 205 21 97 or by post