

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

Trial Description

Title

Registry on data collected from patients with mastocytosis in Europe

Trial Acronym

ECNM Registry

URL of the trial

<http://ecnm.net/homepage/index.php/objectives>

Brief Summary in Lay Language

The primary goal of the ECNM Registry is to collect data from a large number of patients with mastocytosis in Europe over a longer time period (minimum 3 years) in order to learn more about the incidence, biology, pathogenesis, and course of this rare and poorly understood disease.

Brief Summary in Scientific Language

Mastocytosis is a disease characterized by abnormal growth and accumulation of mast cells in i) the skin, ii) in internal organs, or iii) in both the skin and internal organs. Traditionally, mastocytosis is classified as being either cutaneous mastocytosis (CM) or systemic mastocytosis (SM). In cutaneous mastocytosis, mast cell accumulation is only found in the skin. The pure cutaneous form of mastocytosis is usually diagnosed in childhood. By contrast, most patients in adulthood are diagnosed to have systemic mastocytosis. The major aims of the ECNM Registry are to establish solid knowledge about the incidence of mastocytosis, the course of the disease, clinical presentation and course in subvariants, long term survival in various groups of patients, prognostic variables, key markers of disease stability and progression, responses and side effects of various therapies, and long term treatment effects.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00007995**
- Date of Registration in DRKS: **2015/04/16**
- 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.: **466/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **D47.0 - Histiocytic and mast cell tumours of uncertain and unknown behaviour**

Interventions/Observational Groups

- Arm 1: **Observational study to collect data from a large number of patients with mastocytosis in Europe over a longer time period (minimum 3 years) in order to learn more about the incidence, biology, pathogenesis, and course of this rare and poorly understood disease.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological 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

- **Percentage of patients in each category of mastocytosis in Europe**
- **Percentage of patients in each category of mastocytosis in Europe in different European regions**
- **Gender and age distribution of patients with mastocytosis in Europe**

Secondary Outcome

Percentage of patients who show progression to frank aggressive mastocytosis or AHNMD

- **Time to progression**
- **Survival of patients with mastocytosis**
- **Occurrence of mediator symptoms**
- **Determination of risk factors predicting the progression as well as the resulting survival and/or outcome in patients fulfilling the criteria of mastocytosis.**
- **Response to mediator therapy administered in routine**

Countries of recruitment

- **DE Germany**
- **AT Austria**

Locations of Recruitment

- University Medical Center **Medizinische Klinik I, Freiburg im Breisgau**
- University Medical Center **Dermatologie, Köln**
- University Medical Center **Wien**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/10/10**
- Target Sample Size: **2000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

All patients with mastocytosis diagnosed since January 1990 in the participating european centers.

Exclusion criteria

none.

Addresses

■ Primary Sponsor

**Klinik für Innere Medizin IAbteilung für Hämatologie und
Hämostaseologie Medizinische Universität Wien
Mr. Prof. Dr. med. Wolfgang Reinhard Sperr
Währinger Gürtel 18-20
1090 Wien
Germany**

Telephone: **+43 1 40400 4415**

Fax: **+43 1 40400 4030**

E-mail: **wolfgang.r.sperr at meduniwien.ac.at**

URL: [---]*

■ Contact for Scientific Queries

**Universitätsklinikum Freiburg Medizinische Klinik IHämatologie, Onkologie und
Stammzelltransplantation
Mr. Dr. med. univ. Khalid Shoumariyeh
Hugstetter Str. 55
79106 Freiburg im Breisgau
Germany**

Telephone: **0761 270 34010**

Fax: [---]*

E-mail: **khalid.shoumariyeh at uniklinik-freiburg.de**

URL: [---]*

■ Contact for Public Queries

**Universitätsklinikum Freiburg Medizinische Klinik IHämatologie, Onkologie und
Stammzelltransplantation
Mr. Dr. med. univ. Khalid Shoumariyeh
Hugstetter Str. 55
79106 Freiburg im Breisgau
Germany**

Telephone: **0761 270 34010**

Fax: [---]*

E-mail: **khalid.shoumariyeh at uniklinik-freiburg.de**

URL: [---]*

Sources of Monetary or Material Support

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

Universitätsklinikum Freiburg
Hugstetter Str. 55
79104 Freiburg
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

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

Universitätsklinikum Köln
Kerpener Str. 62
50924 Köln
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: www.medizin.uni-koeln.de

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

**Klinik für Innere Medizin I/Abteilung für Hämatologie und
Hämostaseologie/Medizinische Universität Wien**
Mr. Prof. Dr. med. Wolfgang Reinhard Sperr
Währinger Gürtel 18-20
1090 Wien
Germany

Telephone: **+43 1 40400 4415**

Fax: **+43 1 40400 4030**

E-mail: wolfgang.r.sperr@meduniwien.ac.at

URL: [---]*

Status

■ Recruitment Status: **Recruiting ongoing**

■ Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]*

■ Reason, if Reason for Recruiting Stop "Other": [---]*

■ Study Closing (LPLV): [---]*

■ Number of Participants in Germany after Recruiting complete: [---]*

DRKS-ID: **DRKS00007995**

Date of Registration in DRKS: **2015/04/16**

Date of Registration in Partner Registry or other Primary Registry: [---]*

- Total Number of Participants (all Sites worldwide) after Recruiting complete: [---]*

Trial Publications, Results and other documents

Please note:

There are additional attributes available concerning this trial. To open an extended view please [click here](#).