



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

Trial Description

Title

Association of multiple myeloma (MM) with different neoplasms (DN), including second primary malignancies (SPM): systematic analysis in consecutive patients

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

There are numerous innovations in treatment of multiple myeloma (MM), resulting in prolonged overall survival. Nevertheless, long-term complications may comprise the occurrence of different neoplasms (DNs). DNs after e.g. novel agent treatment (e.g. within MM015-study) have been reported, questioning whether specific risk factors predispose to DNs. Albeit previous analyses have focused on subsequent DNs, rather than prior or simultaneously (p/s) DNs (since the latter group needs to live long enough to acquire MM), we here assess both, since p/s DNs is even more pertinent, both phenomena need to be known to MM experts and should allow to define host, MM- and/or therapy-related risks.

Brief Summary in Scientific Language

Multiple myeloma (MM) has envisioned numerous innovations, resulting in prolonged overall survival. Nevertheless, long-term complications may comprise the occurrence of different neoplasms (DNs). DNs after e.g. novel agent treatment (e.g. within MM015-study) have been reported, questioning whether specific risk factors predispose to DNs. SEER and Swedish registry data on DNs have observed overall cumulative incidence rates of 5.1-5.5% in MM. Mailankody et al. showed standardized incidence ratios in MM- and MGUS-patients for AML/MDS of 11.51- and 8.01-fold, respectively. In a previous registry analysis (Hasskarl J. ...Engelhardt M. 2011), we demonstrated an impaired prognosis in MM with subsequent DNs (HR 2.5; 95% CI 1.4-4.4) and that age >60 years was a confounding variable (HR 2.021; 95% CI 1.6-2.6). Albeit previous analyses have focused on subsequent DNs, rather than prior or simultaneously (p/s) DNs (since the latter group needs to live long enough to acquire MM), we here assess both, since p/s DNs is even more pertinent, both phenomena need to be known to MM experts and should allow to define host, MM- and/or therapy-related risks.

Organizational Data

- DRKS-ID: **DRKS00003932**
- Date of Registration in DRKS: **2015/05/28**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: [---]*
- (leading) Ethics Committee Nr.: [---]*

Secondary IDs

Health condition or Problem studied

- ICD10: **C90 - Multiple myeloma and malignant plasma cell neoplasms**

Interventions/Observational Groups

- Arm 1: **There are numerous innovations in treatment of multiple myeloma (MM), resulting in prolonged overall survival. Nevertheless, long-term complications may comprise the occurrence of different neoplasms (DNs). DN after e.g. novel agent treatment (e.g. within MM015-study) have been reported, questioning whether specific risk factors predispose to DN. Albeit previous analyses have focused on subsequent DN, rather than prior or simultaneously (p/s) DN (since the latter group needs to live long enough to acquire MM), we here assess both, since p/s DN is even more pertinent, both phenomena need to be known to MM experts and should allow to define host, MM- and/or therapy-related risks.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**

Study Type: **Non-interventional**

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

Allocation: **Single arm study**

Blinding: [---]*

Who is blinded: [---]*

Control: **Uncontrolled/Single arm**

Purpose: **Prognosis**

Assignment: **Single (group)**

■ Phase: **N/A**

■ Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Prevalence of second malignancies in patients with multiple myeloma

Secondary Outcome

Analysis of riskf factors and outcome

Countries of recruitment

■ DE **Germany**

Locations of Recruitment

■ University Medical Center **Medizinische Klinik I, Freiburg im Breisgau**

Recruitment

■ Planned/Actual: **Actual**

■ (Anticipated or Actual) Date of First Enrollment: **2011/12/01**

■ Target Sample Size: **744**

■ Monocenter/Multicenter trial: **Monocenter trial**

■ National/International: **National**

Inclusion Criteria

■



Gender: **Both, male and female**

- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients with multiple myeloma

Exclusion criteria

none

Addresses

■ Primary Sponsor

**Universitätsklinikum Freiburg
Hugstetter Strasse 49
79095 Freiburg
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: www.uniklinik-freiburg.de

■ Contact for Scientific Queries

**Uniklinik Freiburg
Ms. Prof. Dr. med. Monika Engelhardt Engelhardt
Hugstetter Str. 55
79106 Freiburg
Germany**

Telephone: **+49 761 270 32460**

Fax: **+49 761 270 33180**

E-mail: monika.engelhardt@uniklinik-freiburg.de

URL: [---]*

■ Contact for Public Queries

**Uniklinik Freiburg
Ms. Prof. Dr. med. Monika Engelhardt Engelhardt
Hugstetter Str. 55
79106 Freiburg
Germany**

Telephone: **+49 761 270 32460**



Contact for Public Queries

Uniklinik Freiburg

Ms. Prof. Dr. med. Monika Engelhardt Engelhardt

Hugstetter Str. 55

79106 Freiburg

Germany

Telephone: **+49 761 270 32460**

Fax: **+49 761 270 33180**

E-mail: **monika.engelhardt at uniklinik-freiburg.de**

URL: [---]*

Sources of Monetary or Material Support

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

Universitätsklinikum Freiburg

Hugstetter Strasse 49

79095 Freiburg

Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.uniklinik-freiburg.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/04/30**

Trial Publications, Results and other documents

- Paper **Association of multiple myeloma with different neoplasms: systematic analysis in consecutive patients with myeloma**

* 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.