

Trial Description

Title

A Randomized, prospective pilot trial on exercising during treatment in Fitting Transplant Eligible patients with Symptomatic multiple myeloma

Trial Acronym

REAL-FITNESS

URL of the trial

[---]*

Brief Summary in Lay Language

Exercising in patients with multiple myeloma, who received induction therapy (VCD).

Brief Summary in Scientific Language

Symptomatic MM at Initial diagnosis and planned induction therapy VCD (Bortezomib, Cyclophosphamide, Dexamethasone). Two arms receiving/not receiving exercising.

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00022250**
- Date of Registration in DRKS: **2020/10/05**
- 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.: **173/20** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C90.0 - Multiple myeloma**

Interventions/Observational Groups

- Arm 1: **exercising**
- Arm 2: **no exercising**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject**
- Control: **Control group receives no treatment**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Feasibility with ist aim of a multicentric, randomised clinical trial.

Secondary Outcome

(1) Evaluation of Revised Myeloma Comorbidity Index (R-MCI) due to differences in physical active vs. inactive MM-patients. (2) Event Free Survival (EFS).

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2021/01/01**
- Target Sample Size: **30**
- 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

(1) Symptomatic MM at initial diagnosis. (2) Planned induction therapy with VCD followed by transplantation at UKF.

Exclusion criteria

(1) Spinal cord compression or unstable fractures. (2) Severe cardiac diseases or arrhythmia (NYHAE 3-4). (3) Chronic cardiac diseases (NYHAE 3-4). (4) Other severe diseases not allowing physical activity and exercising (e. g. severe neurological disorder).

Addresses

■ Primary Sponsor

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

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

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

■ Contact for Scientific Queries

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

Telephone: **+4976127032460**

Fax: **+497612709633180**

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

URL: [---]*

■ Contact for Public Queries

**Universitätsklinikum Freiburg
Ms. M. A. Mandy-Deborah Möller
Breisacher Str. 115
79106 Freiburg
Germany**

Telephone: **+4976127078171**

Fax: [---]*

E-mail: **mandy-deborah.moeller 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 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: [---]*

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

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.