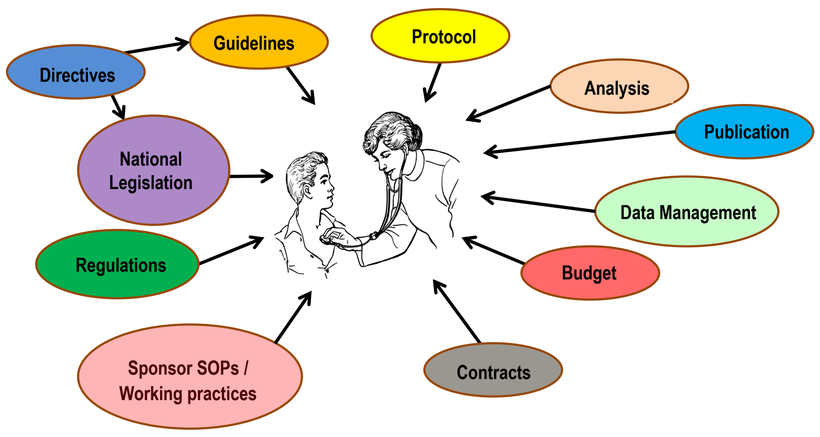
EBMT CTO

Clinical trials and non-interventional studies

Clinical Trials and Non Interventional Studies

The EBMT CTO is based in Leiden. The CTO offers the following services for EBMT sponsored trials:

- Protocol design and feasibility
- Competent Authority and Ethics Committee submissions
- IMP management
- Pharmacovigilance, including IDMC
- Recruitment and retention services
- Monitoring and centre/vendor oversight
- Contract negotiation and budget management
- Quality management and auditing
- Data management and statistics
- Report writing



The CTO runs the following types of prospective clinical trials:

- Phase II-IV, including post-authorisation safety studies
- Investigator initiated trials
- Non Interventional Studies (NIS)

RIC versus MAC followed by allogeneic HSCT for patients with MDS (RICMAC)

Nicolaus Kröger *et al.*

Purpose and methods

To compare busulfan-base reduced intensity conditioning regimen (RIC) to myeloablative regimen (MAC) prior to allogeneic transplantation in in a total of 129 patients with myelodysplastic syndrome (MDS) within a prospective, multicentre, open label randomized phase III trial.

Results

Engraftment was comparable between both groups. The cumulative incidence (CI) of acute GvHD II-IV was 32.3% after RIC and 37.5% after MAC (p = 0.35). The CI of chronic GvHD was 61.6% after RIC and 64.7% after MAC (p = 0.76). The CI of NRM after 1 year was 17% (95% CI 8-26%) after RIC and 25% (95% CI 15-36%) after MAC (p = 0.29). The CI of relapse at 2 years was 17% (95% CI 8-26%) after RIC and 15% (95% CI 6-24%) after MAC (p = 0.6), resulting in a 2 year relapse-free and overall survival of 62% (95% CI 50-74%) and 76% (95% CI 66-87%) after RIC and 58% (95% CI 46-71%) and 63% (95% CI 51-75%) after MAC (p = 0.58 and p = 0.08, respectively).

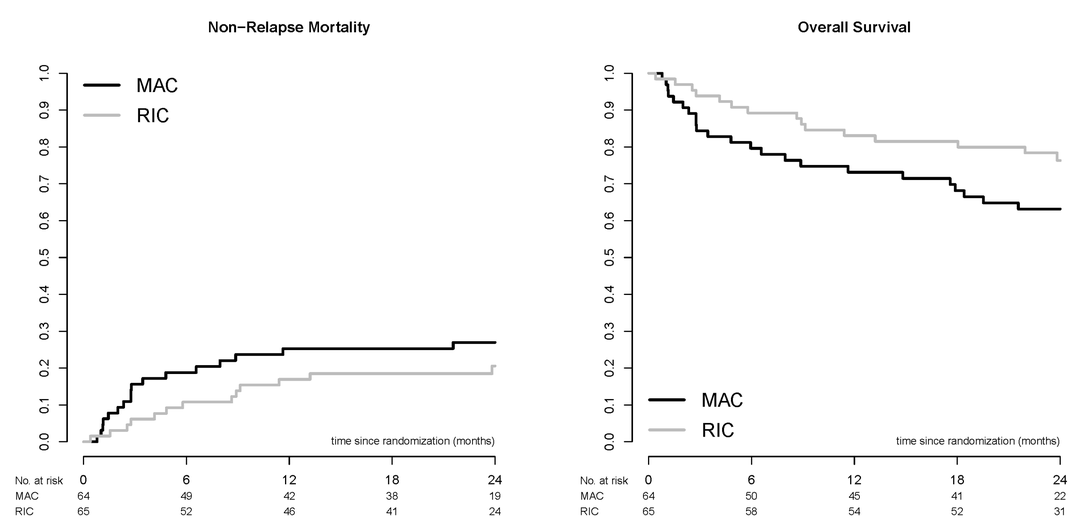


Figure (left) non-relapse mortality and (right) overall survival according to intensity of conditioning regimen

Conclusion

RIC resulted in at least similar 2 year relapse-free and overall survival as MAC in patients with MDS or sAML.

Rituximab in patients undergoing autologous HSCT for Relapsed Follicular Lymphoma (LYM-1)

Ruth Pettengell

Purpose and methods

To assess safety and efficacy of rituximab (MabThera) as in vivo purging before transplantation and as maintenance treatment immediately after high-dose chemotherapy and autologous stem-cell transplantation in patients with relapsed follicular lymphoma within a randomised study with a factorial design.

Results

This trial closed to recruitment in 2006 after recruiting 280 patients. Data were published in Journal of Clinical Oncology in 2013. Long term survival data was collected until end of Dec 2016 and the study was closed at the end Feb 2017. Data is currently being analysed for ICML abstract and an updated manuscript.

Thank you!

We would like to thank all centres that have supported this study for the last 18 years.

Successful collaboration with Merck on the MK-8228 trial: Letermovir for prevention of CMV

Purpose and methods

To evaluate Safety and Efficacy of MK-8228 (Letermovir) for the Prevention of Human Cytomegalovirus (CMV) Viremia and/or Disease in Adult CMV Seropositive Allogeneic HSCT subjects. One third of patients were randomised to receive placebo, two thirds Letermovir.

Results

In this Merck (MSD) sponsored trial (73 sites, 20 countries), EBMT supported 49 sites worldwide by providing a recruitment and retention service, including hosting annual workshops and targeted teleconferences. Recruitment went exceptionally well and ended 3 months earlier than planned. Data is being analysed for publication.

Special thanks

Per Ljungman and Rafa Duarte for all their efforts to make this trial a success!

The CTO team

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The London Clinical Trials Office will close down as per the 31st of March.

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