

European Society for Blood and Marrow Transplantation

Transplant Complications Working Party

Chair: Grzegorz BasakSecretary: Zinaida PericStatistician: Christophe PeczynskiGVHD subcommittee: Olaf PenackLate Complications subcommitee: Hélène SchoemansRegimen-related toxicity & supportive care subcommitee: Christian Koenecke

CALL for DATA

Survey: EBMT Patient Engagement Context Analysis

PI: Helene Schoemans & Bregje Verhoeven

Joint project : Transplantation Complications Working Party of the EBMT, Patient Advocacy Committee of the EBMT & EBMT Patient Engagement Task Force Aim: To perform context analysis to understand the current point of view of HCT and cell therapy stakeholders (health care providers, industry staff, government officials, patients, donors and caregivers) regarding the engagement of patients in HCT and cell therapy research.

CALL for FU-DATA

Non interventional study: **EASIX to predict alloSCT outcome.**

PI: Olaf Penack and Thomas Luft.

Primary objective: To estimate the prognostic ability of EASIX before conditioning (i.e. at the day of hospital admission for alloSCT), at day of transplantation, at day 14 and at day 28 on 1-year NRM.

Inclusion Criteria:

First alloSCT in children and adults with PBSCs (all donor types).

Methods: An online survey sent by email to the participants to the EBMT Annual Meeting 2020, before and after the meeting, and promoted during the meeting by QR code.



CALL for DATA

Non interventional study: Prospective non-interventional observational study on the incidence, severity, management and outcome of sinusoidal obstruction syndrome/ veno-occlusive disease of the liver in allogeneic haematopoietic stem cell transplantation in adult patients.

PI: Tapani Ruutu.

The landscape of sinusoidal obstruction syndrome / veno-occlusive disease of the liver (SOS/VOD) has changed considerably during the recent years. There have not been any satisfactory means to predict in an early phase which patients will develop severe SOS/VOD. Early prediction has become particularly important as effective treatment has become available, and early treatment has been shown to result in improved outcome.

Primary Objective: To determine the current incidence and outcome of SOS/

Previous autoSCT is not an exclusion criterion.

Patients with acute leukemia, MDS, MPN or lymphoma (all disease stages). Myeloablative and dose-reduced conditioning (all types of GVHD prophylaxis).

Expected study period: February 1st 2018. Recruitment was closed by May 31st 2020. Follow up will be till day +365 after alloSCT. 267 are registered, and one year follow-up is due

CALL for FU-DATA

Non interventional study: Complications of T cell-repleted haploidentical stem cell transplantation with post-transplant cyclophosphamide.

PI: Grzegorz Basak.

<u>**Primary objective:**</u> To document incidence and frequency of infectious and noninfectious complications after posttransplant cyclophosphamide-based haploSCT. <u>**Inclusion Criteria:**</u>

Adult patients (>=18y old at time of transplant).

Patients in whom T cell-replete haploidentical stem cell transplantation with posttransplant cyclophosphamide has been performed between November 2017 and December 2019.

Current status: 10 centres participating, 136 patients enrolled

Expected study period: 2017-2021 : inclusion was closed by the 31st December 2019 and 2 years follow up is due.

VOD in allogeneic transplantation in adult patients This study would serve as validation for the new EBMT criteria and severity grading.

SOS/VOD.

Current Status:

- The fisrt step of the study allow collect the orruence of the SOS/VOD for 97 and to confirm the absence of SOS/VOD for 1853 patients
- The second step, the data collection is ongoing, up to know, details information on the SOS/VOD has been collected for 67 patients

CALL for DATA

A cross-sectional study on the Sexual Function of Adult Survivors and their partners 3 and 15 years Post allogeneic Stem Cell Transplantation.

PI: Corien Eeltink and Jacqui Stringer

Sexual dysfunction has increasingly been recognized as a complication of allogeneic stem cell transplantation with negative impact in their quality of life. The sexual partner might also contribute to sexual dysfunction or to sexual inactivity. Furthermore, patients and their partners have reported to be disappointed by the lack of information, support, and practical strategies provided by health professionals to assist them to cope with the sexual changes they experienced.

Primary objective:

CALL for DATA

Retrospective study: Fecal microbiota transplantation in the treatment of graftversus-host disease.

PI: <u>Jarosław Biliński</u>.

Fecal Microbiota Transplant restores the physiological diversity of the gut flora rebuilding the so called "colonization resistance" to pathogenic microorganisms. It was found that FMT may decolonize the gastrointestinal tract from highly antibioticresistant bacteria. Manipulation of the intestinal microbiota by FMT may also influence the immune system and dampen immune-mediated reactions to target tissues such as gut, liver, and skin.

<u>Primary Objective:</u> To describe the clinical efficacy of FMT used for treatment of GvHD in a retrospective series of patients. Clinical efficacy is defined as clinical response (complete and partial response) at day 28 after start of FMT.

Study population: Adult patients after alloHCT who developed gastrointestinal graft-versus-host disease and were treated with FMT.

Current Status:

- The 1st step center identifications :all EBMT centers who perform more than 99 allo transplant since 2010 have been contacted. 56 centers answered, 12 agreed for a total of (49) expected patients and 39 refused to participate mostly because they don not perform FMT.
- The 2nd step, the data collection started in May 2019. 5 centers send data for 28 patients. Data quality queries are ongoing.

To explore patients' and their partners' opinions on their sexual functioning 2 till 4 and 14 till 16 years post Allogeneic HSCT To evaluate if discussion, adequate help or counseling with regard to sexual function between the health care provider and the survivor has taken place

Inclusion criteria:

Age \geq 18 years

Time of follow up 2 - 4 or 14 - 16 years after HSCT at time of data collection Ability to read and write in English, French, German, Italian or Dutch No cognitive impairment

Current Status:

Seven sites are actively enrolling and another 3 sites are open but not yet enrolling patients and 3 are busy with the EC submissions. 125 patients have been enrolled, so far of the 311 are required.

* This study is still recruiting *

Transplant Complications Working at the EBMT Annual Meeting Madrid

Oral session 1 - Early complications after transplantation 1 Monday 23/03/2020, 09:00 – 10:30 , Room: Sala Retiro Transplant Complications Working Party Session Monday 23/03/2020, 11:00 – 12:30, Room : Sala Colón Transplant Complications Working Party Business Meeting Tuesday 24/03/2020, 07:00 – 09:00, Room : N113 Oral session 9 - Early complications after transplantation 2 Tuesday 24/03/2020, 16:30 – 18:00, Room : Hall B (Exhibition Area) Oral session 19 - Late effects and quality of life Wednesday 25/03/2020, 11:00 – 12:30, Room: Sala Neptuno

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