Transplant Complications Working Party

European Society for Blood and Marrow Transplantation

Chair: Grzegorz Basak
Secretary: Zinaida Peric
Statistician: Christophe Peczynski
Study Coordinator : Alenca Harrington

GvHD Subcommittee: Hildegard Greinix
Late Complications Subcommittee: Nina Salooja
Regimen-related toxicity & supportive care Subcommittee: Tapani Ruutu
Nurse Lead: Diana Greenfield

TCWP CALL FOR PARTICIPATION

SFAST *Leiden Data Office*

A joint study between the TCWP and the Nurse Group of EBMT

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:

1) To explore patients' and their partners' opinions on their sexual functioning 2 till 4 and 14 till 16 years post Allogeneic HSCT
2) 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 ≥ 18 years
- Time of follow up 2 - 4 or 14 - 16 years after transplantation at time of data collection
- Ability to read and write in English, French, German, Italian or Dutch
- No cognitive impairment

*** This study is still recruiting ***

TCWP CALL FOR DATA

Uric Acid *Leiden Data Office*

Non interventional study: **Association between uric acid levels and GvHD**

PI: **Olaf Penack.**

It has been demonstrated in preclinical models that uric acid contributes to GvHD. In this prospective study, uric acid levels are assessed of patients undergoing allo-SCT. The uric acid levels will be correlated to clinical outcome.

Primary objective: To assess if uric acid levels are associated with incidence and severity of Acute GvHD

Inclusion criteria:

- First allo-SCT from HLA-matched sibling donors given stem cell grafts(BM or PB)
- Patients with acute leukemia, MDS or lymphoma
- Myeloablative or dose-reduced non-myeloablative conditioning

Current status

22 sites participating, hoping to collect **400** patients. Currently **390** patients enrolled.

Please send in your data

TCWP Meetings

EBMT Annual Meeting Lisbon: TCWP Session
Monday, 19th March, 09:00-10:30
Room: 3C
EBMT Annual Meeting Lisbon: TCWP Business Meeting
Tuesday, 20th March, 07:00-09:00
Room: 5C

TCWP Educational Meeting in Zagreb, Croatia
8th November 2018 - 10th November 2018

TCWP Paris Data Office

All studies from 2017 onwards will be coordinated by the Paris Data Office. The TCWP study coordinator is Alenca Harrington: alenca.harrington@upmc.fr however studies started before 2017 by the Leiden Office will stay with the previous study coordinator, Steffie van der Werf: S.M.van_der_Werf@lumc.nl

TCWP CALL FOR PARTICIPATION

T-replete haplo with PTCy *Paris Data Office*

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

PI: **Grzegorz Basak.**

Primary objective: To document incidence and frequency of infectious and non-infectious complications after posttransplant cyclophosphamide-based haploSCT.

Inclusion Criteria:

- 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 November 2018.

Expected study period: 2017-2020 (registration: 2017-2018, 2 years follow up).

*** This study is recruiting ***

EASIX *Paris Data Office*

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).
- 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. It is expected that recruitment will be closed by May 31st 2019. Follow up will be till day +365 after alloSCT.

*** This study is recruiting ***

New TCWP Studies

SOS/VOD *Paris Data Office*

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/ VOD in allogeneic transplantation in adult patients

This study would serve as validation for the new EBMT criteria and severity grading.

Study population: Adult patients with SOS/VOD.

Fecal Microbiota *Paris Data Office*

Retrospective study: **Fecal microbiota transplantation in the treatment of graft-versus-host disease**.

PI: **Jarosław Biliński.**

Fecal microbiota transplantation has been more and more frequently used for the treatment of resistant and refractory Clostridium difficile colitis. It has been also confirmed that FMT can be used for eradication of gut colonisation by antibiotic-resistant bacteria. Both approaches have been increasingly used also in the setting of allogeneic hematopoietic cell transplantation. In this clinical entity it has been shown to have immunomodulatory properties with potential to cause remission of gut graft versus host diseases. Several case series have been described in the literature and the prospective clinical trials are ongoing.

Primary Objective: 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.