

TCWP CALL FOR PARTICIPATION

SFAST Leiden Data Office

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

Current Status:

Six sites are actively enrolling and another six are busy with the EC submissions. 89 patients have been enrolled so far of the 311 are required.

* This study is still recruiting *

TCWP CALL FOR DATA

ATG survey Paris Data Office

Survey:

Evaluate the current clinical practice in EBMT centres concerning the use of ATG as GVHD prophylaxis after allogeneic HCT due to haematological malignancies

PI: **A. Piekarska**

Primary Objective:

Description of the current use of ATG as GvHD prevention in EBMT centres

Inclusion Criteria:

ATG use as GVHD prophylaxis

Current status:

Up to 19/02/2019 **105** centers have responded, hoping to collect at least 100 responses

TCWP Meetings

EBMT Annual Meeting Frankfurt
Monday, 25th March, 11:00-12:30
Room : Conclusio 1+2

EBMT Annual Meeting Frankfurt
Tuesday, 26th March, 07:00 – 09:00
Room : Illusion 3

1st EBMT GVHD Summit in Warsaw, Poland
16th May – 18th May 2019

TCWP CALL FOR PARTICIPATION

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. So far 108 registrations and 60 D-100 questionnaires have been collected

* This study is recruiting *

T-replete haplo with PTC 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 December 2019.

Current status: 9 centres participating, 76 patients enrolled, hoping to reach 300

Expected study period: 2017-2021 (registration: 1st November 2017- 31st December 2019, 2 years follow up).

* 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: **Jaroslav Biliński.**

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 antibiotic-resistant 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.

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.

Current Status: so far 24 patients identified

TCWP Paris Data Office

All studies from 2017 onwards will be coordinated by the Paris Data Office. The TCWP study coordinator is Ivan De Marino : ivan.de_marino@upmc.fr