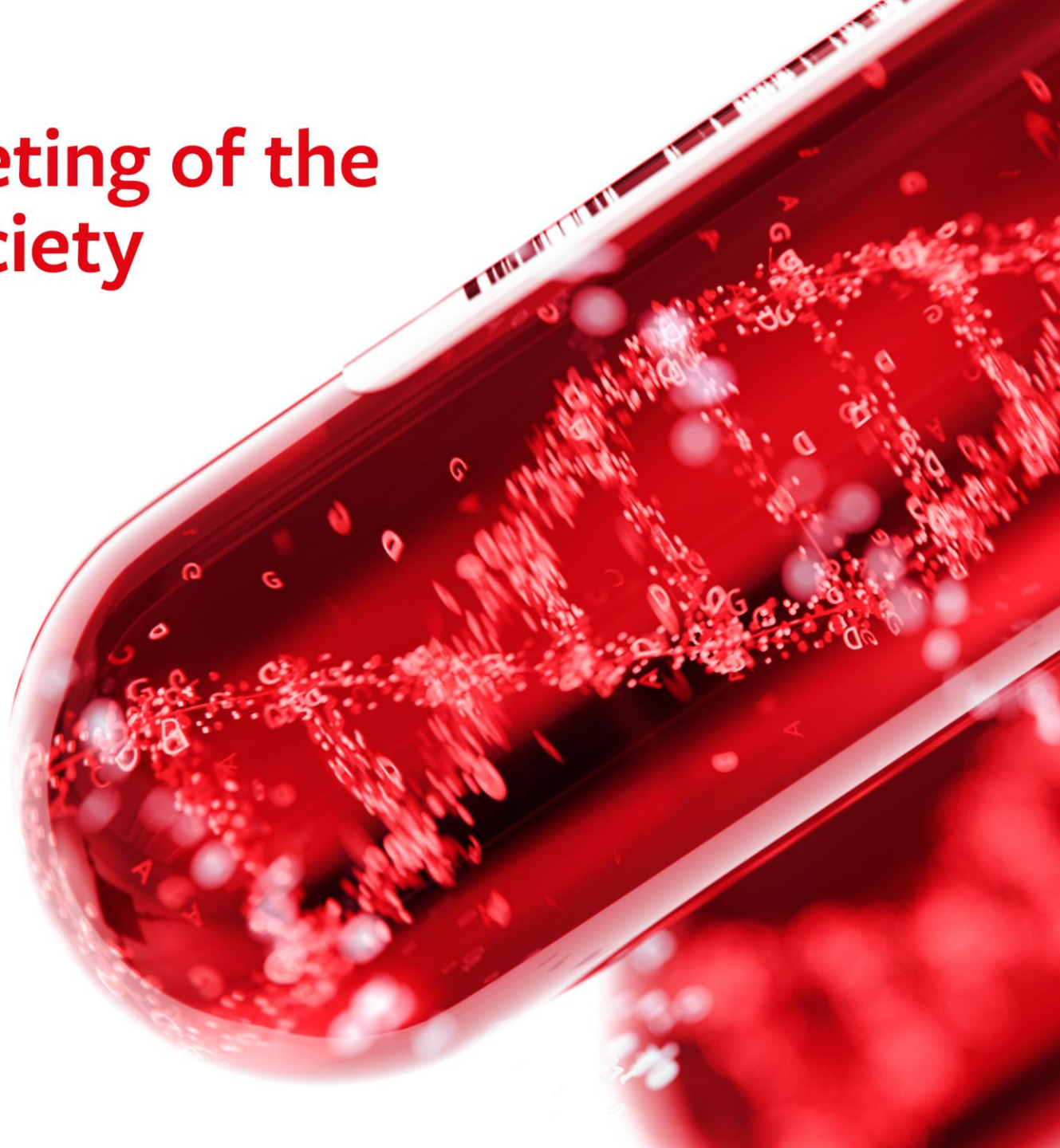
39th General Annual Meeting of the Belgian Hematology Society

February 2-3, 2024
Dolce La Hulpe, Brussels

face-to-face Meeting



BHS
Belgian Hematology Society

BHS transplantation committee

Tessa Kerre, Ghent University Hospital
Carlos Graux, UCL

39th General Annual Meeting of the Belgian Hematology Society

BHS Belgian Hematology Society

February 2-3, 2024
Dolce La Hulpe, Brussels

Members

Chair: Tessa Kerre, UZ Gent

Co-chair: Carlos Graux, UCL

Members: representatives from all Belgian transplant centers

CRA:

Josephine Muller (CRA Ulg)

Email address: clinicaltrials@bhs.be

Members

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Overview past and current trials

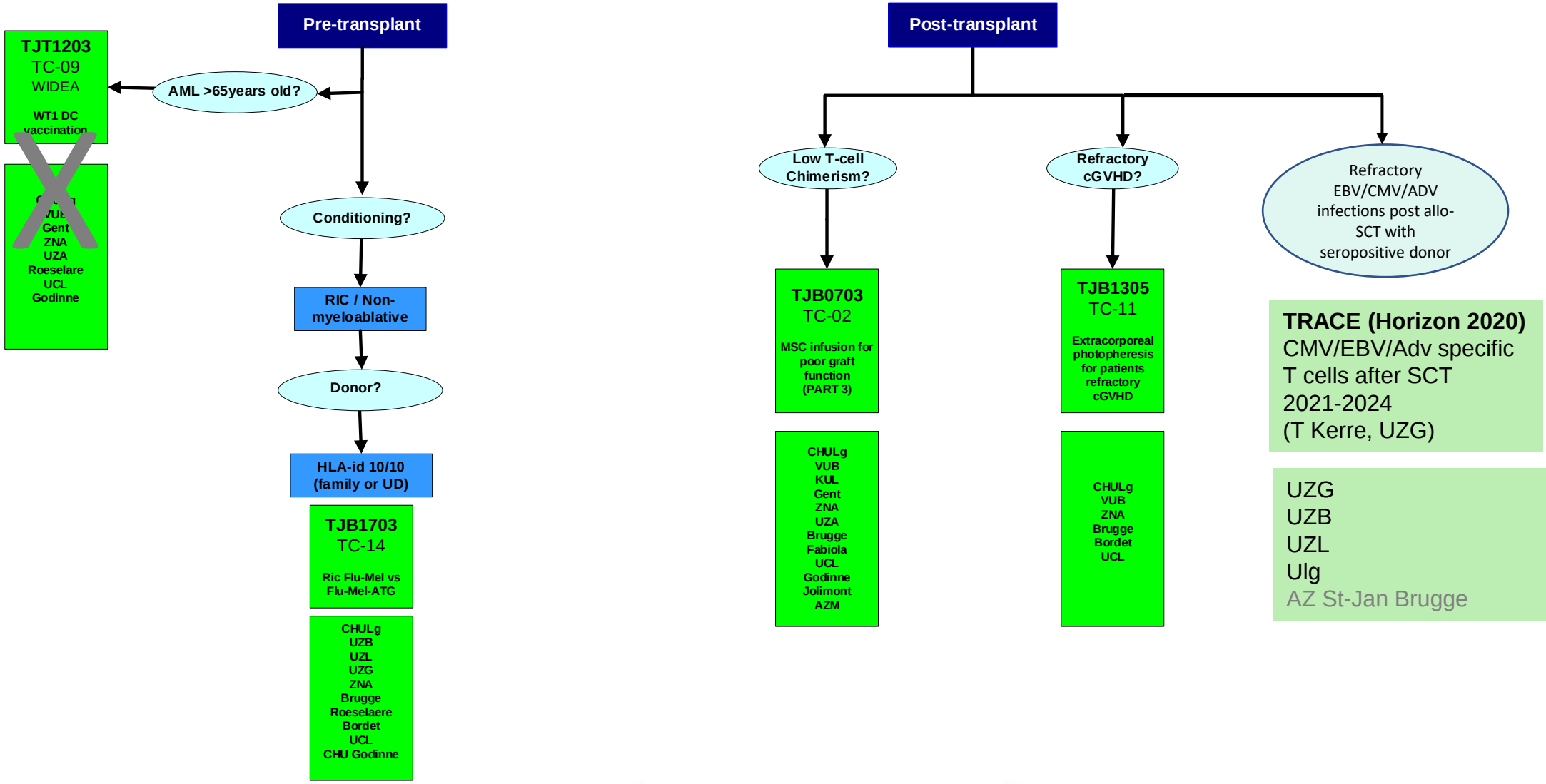
End of Study:

- TJB0603 (EBMT)
- TJB0702 (Flu-TBI vs TLI-ATG)
- TJB0905 (MSC CB)
- TJB0909 (MSC mismatched)
- TJB1010 (HOVON96)
- TJB1016 (Rapa vs MMF)
- TJB1122 (Busulfan)
- TJB1302 (DLI Vidaza)
- TJT1401 (CMV)

Recruiting Studies:

- TJB0703 (MSC poor chimerism)
- TJT1203 (WIDEA) → AML committee
- TJB1305 (Photopheresis)
- TJB1703 (FM-PTCy vs FM-ATG)
- TRACE

Current trials



TRACE (Horizon 2020)
CMV/EBV/Adv specific T cells after SCT
2021-2024
(T Kerre, UZG)

UZG
UZB
UZL
Ulg
AZ St-Jan Brugge

What did we do in 2023?

Publications on clinical trials

Accepted 2022, published 2023

Multipotent mesenchymal stromal cells as treatment for poor graft function after allogeneic hematopoietic cell transplantation: a multicenter prospective study

Sophie Servais, Frédéric Baron, Chantal Lechanteur, Laurence Seidel, Etienne Baudoux, Alexandra Briquet, Dominik Selleslag, Johan Maertens, Xavier Poire, Wilfried Schroyens, Carlos Graux, Ann De Becker, Pierre Zachee, Aurélie Ory, Julie Herman, Tessa Kerre and Yves Beguin

Frontiers Immunology 2023, Feb 1; 14:1106464

What did we do in 2023?

Publications on clinical trials

Submitted

Feasibility of co-transplantation of umbilical cord blood and third-party mesenchymal stromal cells after (non)myeloablative conditioning in patients with haematological malignancies.
Ann De Becker, Tessa Kerre, Johan Maertens, Frédéric Baron, Carlos Graux, Ivan Van Riet, Chantal Lechanteur, Etienne Baudoux, Yves Beguin and Rik Schots, on behalf of the Transplant Committee of the Belgian Hematology Society.
Rejected by Cytotherapy
→ resubmitted to another journal

What did we do in 2023?

Publications on guidelines

none

Regulatory affairs

- SOP Belgian Transplant Registry in collaboration with the Belgian Cancer Registry (Y Beguin, Ulg) --> EBMT benchmarking

- Support letter for reimbursement of Prevemys post transplant, extension 2 months (D200) for risk groups.

What are our future projects and ideas?

Publications

- MSC in double UCB SCT (A. De Becker, UZB): submitted
- In vitro and in vivo dose relevant AZA effect on Tregs subpopulations: applied to post-HSCT relapsing AML/MDS (C. Cassius, X Poiré, C. Graux, UCL): in preparation
- Busulfan dosage (T. Kerre, A. Delie, UZG): in preparation

Guidelines

- Update Belgian vaccination guidelines post transplant / CAR-T: general guidelines for hematological patients in collaboration with the other committees? Or two separate publications? – Workshop by Société francophone de greffe de moelle et de thérapie cellulaire (SFGM-TC) – Y. Beguin – C. Graux – X. Poiré – F. Van Obbergh – K. Beel – T. Kerre
- It's all about the numbers: Belgian guidelines on optimal numbers for both CD34 and CD3 for (autologous and) allogeneic stem cell transplantation, depending on underlying disease, donor and conditioning. – D. Deeren

What are our future projects and ideas?

Regulatory affairs

Reimbursement photophoresis (P Lewalle, Bordet, Y Beguin, Ulg)

Reimbursement vaccination after stem cell transplantation, Wallony (F Van Obbergh, UCL)

Reimbursement chimerism analysis (A Delie, UZG)

What are our future projects and ideas?

Clinical trials: new proposals for 2023-2024

- Fludarabine dosing study for RIC SCT (A Delie, UZG): budget OK, EC final phase)
- Fludarabine dosing study in LD chemotherapy before CAR-T infusion (A Delie, UZG): budget OK, EC final phase)
- KIR typing in haplo-identical donors (Dries Deeren, Ann de Becker) KIR typing (prospective trial; Sanofi grant awarded, HLA lab UZB still interested)
- VWF as predictive biomarker for endothelial dysfunction (EBMT poster 2023) in SCT → extend to CAR T-cell therapy (Guillaume Dachy - Xavier Poiré): The project would to propose to measure VWF antigen (VWF:Ag) and ristocetin cofactor activity (VWF:RCo) at the day of hospitalization and then study the outcome at +/- day + 50, especially in terms of infections and ICAHT.
- AZATARG trial for AML relapsed after SCT (X Poiré, UCL): pending budget – on hold

What are our future projects and ideas?

Research project proposal 2023 - report

CRA support for the PI's of the currently recruiting trials: 1000 euro/included patient

- TJB0703 (MSC poor chimerism) (F. Baron, Ulg) → support needed: 2-3 patients expected to be enrolled in 2024
- TJB1703 (FM-PTCy vs FM-ATG) (F. Baron, Ulg) → support needed: 15-20 patients expected to be enrolled in 2024
- TRACE → no support needed (support by Horizon 2020)
- TOTAL # patients: 20 → 20.000 euro for 2023 → 10.000 euro

What are our future projects and ideas?

Research project proposal 2024

CRA support for the PI's of the currently recruiting trials: 1000 euro/included patient

- TJB0703 (MSC poor chimerism) (F. Baron, Ulg) → no support needed (no patients expected to be enrolled in 2024)
- TJB1703 (FM-PTCy vs FM-ATG) (F. Baron, Ulg) → support needed: 15 patients expected to be enrolled in 2024 → TOTAL # patients: 15-20 → 15.000 euro for 2024

  Done / ongoing

  - Inclusion and randomization of 2 additional patients in January
  - CRF follow-up and SAE management of all patients

  To be done

  - Plan to include 10-15 additional patients this year
  - Preparation of the data and presentation for the 2024 DSMB meeting (to be planned in March 2024)
  - Preparation and submission of the Development Safety Update Report (DSUR) n° 5 (March 2024)
  - Transition of the current study to the Clinical Trials Information System (CTIS)
  - Closure of the TJB0703-TC02 "MSC for poor graft function study

What are our future projects and ideas?

Research project proposal 2024

CRA support for the PI's of the currently recruiting trials: 1000 euro/included patient

- TJB TBD: VWF as predictive biomarker for endothelial dysfunction (EBMT poster 2023) in SCT → extend to CAR T-cell therapy
  - VWF:Ag and VWF: RCo assays cost 20 euros: can this also be budgeted for the BHS?
  - Patients planned to enroll:
    - allogeneic bone marrow transplant cohort:
      - Inclusion criteria: all types of donors, underlying hematologic diseases and conditioning regimens.
      - Exclusion criteria: known Von Willebrand disease (type I/II/III) and Hemophilia A.

      → 238 patients to recruit at least 93 patients in both groups, based on our preliminary analyses / 2years: 4760 € / 2y
    - CAR T cells cohort
      - Inclusion criteria: all patients 16 years old, with B cell NHL
      - Exclusion criteria: Von Willebrand disease (type I/II/III) and Hemophilia A.

      → 80 patients to include / 2 years: 1600€ / 2y
  - Study coordinator: 8500€ (40 days of work distributed on a foreseen period of inclusion 2 years) → 4.250 / year
  - Total budget: 14 860€ / 2 y → 7.430 for 2024

What are our future projects and ideas?

Research project proposal

CRA support for new trials: 10.000 euro/trial

- no support needed at this moment

Writing grant proposal

- no support needed at this moment

Thank you for you attention!