Mirasol® Pathogen Reduction Technology (PRT) System Clinical Data Overview

TERUMO BLOOD AND CELL TECHNOLOGIES

Routine use data and clinical trials support the safety and effectiveness of Mirasol-treated blood products.

Introduction

- In routine use **since 2009,** Mirasol is now used in **37 countries and 200 active centers** in Europe, the Middle East, Latin America, and Asia Pacific.
- **No serious adverse events** have been reported; more than 2.5 million Mirasol disposable kits have been sold and data has been published about more than 190,000 transfusions of Mirasol-treated products.
- All the clinical studies evaluating Mirasol and the routine use **data confirmed the safety and effectiveness** of Mirasol-treated blood products.

At Terumo Blood and Cell Technologies, we remain committed to advancing global blood safety, including continuing to research and track the use of Mirasol.

Routine use data demonstrates the safety and effectiveness of Mirasol-treated products.

Hemovigilance (HV) is an integral part of quality management in a blood system, allowing for continual improvement in the quality and safety of blood components and transfusion processes.

	Active HV Warsaw 2011 to 2013[1]	Passive HV Multiple Sites 2010 to End of 2015[2]
Number of countries where data was collected	1	6
Total number of transfusions	11,756	> 188,000
Number of platelet units transfused	7,827	> 91,000
Number of fresh frozen plasma units transfused	3,929	> 96,000
Increase in adverse reaction rates?	**No**	**No**
Conclusion	**Proven safe for patients**	**Proven safe for patients**

Many clinical studies also demonstrated the safety and efficacy of Mirasol-treated products.

Results from these studies tracking nearly 1,300 patients have been peer-reviewed and published or accepted for publication.

Study Name or Design	Number of Patients	Study Population	Design	Primary Endpoints
PREPAReS[3] Efficacy/safety of Mirasol-treated PLTs	469	Thrombocytopenic patients	Randomized controlled clinical trial	No. and % episodes of bleeding ≥ WHO grade 2
IPTAS[4] Efficacy/safety of Mirasol-treated PLTs	196	Thrombocytopenic patients needing ≥ 2 PLT transfusions	Single-blind, randomized controlled clinical trial	% patients with bleeding ≥ WHO grade 2
Safety/efficacy[6]	19	Therapy-induced thrombocytopenic patients	Prospective, observational open-label study	$CCI_{1\ hour}$ $CCI_{24\ hours}$
Safety/efficacy[7]	146	Thrombocytopenic patients	Retrospective/prospective observational open-label study	$CCI_{24\ hours}$

Study Name or Design	Number of Patients	Study Population	Design	Primary Endpoints
Safety/efficacy of Mirasol-treated PLTs transfused in children[8] Routine setting	137	Therapy-induced thrombocytopenic patients	Retrospective, open-label, single-center study	% patients with bleeding on any day of PLT support No. of ARs
Performance/safety of Mirasol-treated PLTs[9] Routine setting	54	Thrombocytopenic patients	Prospective observational study	% $CCI_{1\ hour} \geq 7{,}500$ % $CCI_{24\ hours} \geq 4{,}500$
AIMS[10] Reduction in TTM with Mirasol-treated WB	214	Adult patients who required up to two WB transfusions within 3 days	Prospective, randomized, parallel-group, double-blind, controlled, single-center study	Efficacy of Mirasol-treated WB in preventing TTM
IMPROVE[11] Performance of RBCs derived from Mirasol-treated WB	11	Healthy adult volunteers	Recovery and survival of RBCs resulting from Mirasol-treated WB using three different UV light energies (22, 33 and 44 J/mL RBC)	Recovery and survival
IMPROVE II[12] Performance of RBCs derived from Mirasol-treated WB	24	Healthy adult volunteers	Recovery and survival of RBCs resulting from Mirasol-treated WB at 80 J/mL RBC	Recovery and survival
Total number of patients	**1,270**			

KEY: AR = adverse reaction; CCI = corrected count increment; FFP = fresh frozen plasma; PLT = platelet; RBC = red blood cell; TTM = transfusion-transmitted malaria; WB = whole blood; WHO = World Health Organization.

References

[1]Letowska M, Przybylska Z, Piotrowski D, et al. Hemovigilance survey of pathogen-reduced blood components in the Warsaw region in the 2009 to 2013 period. *Transfusion.* 2016;56 (suppl 1):S39-S44.

[2]Piotrowski D, Przybylska-Baluta Z, Jimenez-Marco T, et al. Passive haemovigilance of blood components treated with a riboflavin-based pathogen reduction technology. *Blood Transfus.* 2018;16(3):348-351.

[3]Van der Meer PF, Ypma PF, van Geloven N, et al. Hemostatic efficacy of pathogen-inactivated versus untreated platelets: a randomized controlled trial. *Blood.* 2018.

[4]Rebulla P, Vaglio S, Beccaria F, et al. Clinical effectiveness of platelets in additive solution treated with two commercial pathogen-reduction technologies. *Transfusion.* 2017;57(5):1171-1183.

[5]Mirasol Clinical Evaluation Study Group, Goodrich RP. A randomized controlled clinical trial evaluating the performance and safety of platelets treated with Mirasol pathogen reduction technology. *Transfusion.* 2010;50(10):2362-2375.

[6]Drawz SM, Marschner S, Yañez M, et al. Observational study of corrected count increments after transfusion of platelets treated with riboflavin pathogen reduction technology in additive solutions. *Transfusion.* 2015;55(7):1745-1751.

[7]Kaplan A, Lindgren B, Marschner S, et al. Evaluation of the post-transfusion platelet increment and safety of riboflavin-based pathogen reduction technology (PRT) treated platelet products stored in platelet additive solution for 5 days or less versus 6-7 days. *Transfus Apher Sci.* 2016;54(2): 248-252.

[8]Trakhtman P, Karpova O, Balashov D, et al. Efficacy and safety of pathogen-reduced platelet concentrates in children with cancer: a retrospective cohort study. *Transfusion.* 2016;56 (suppl 1):S24-S28.

[9]Vilariño MD, Castrillo A, Campos A, Kilian R, Villamayor M, Cardoso M. Assessment of the clinical performance of platelet concentrates treated by pathogen reduction technology in Santiago de Compostela. *Transfus Med Hemother.* 2017;44:5-9.

[10]Allain JP, Owusu-Ofori AK, Assennato SM, Marschner S, Goodrich RP, Owusu-Ofori S. Effect of Plasmodium inactivation in whole blood on the incidence of blood transfusion-transmitted malaria in endemic regions: the African Investigation of the Mirasol System (AIMS) randomised controlled trial. *Lancet.* 2016;387(10029):1753-1761.

[11]Cancelas JA, Rugg N, Fletcher D, et al. In vivo viability of stored red blood cells derived from riboflavin plus ultraviolet light-treated whole blood. *Transfusion.* 2011;51(7):1460-1468.

[12]Cancelas JA, Slichter SJ, Rugg N, et al. Red blood cells derived from whole blood treated with riboflavin and ultraviolet light maintain adequate survival in vivo after 21 days of storage. *Transfusion.* 2017;57(5):1218-1225.

Availability of product is based on regulatory approval in each country. Not approved for sale in the U.S. Product and protocol availability varies by country.

To learn more about advancing global blood safety with Mirasol, contact your Terumo Blood and Cell Technologies representative.

TERUMO BLOOD AND CELL TECHNOLOGIES

Terumo Blood and Cell Technologies is a medical technology company. Our products, software, and services enable customers to collect and prepare blood and cells to help treat challenging diseases and conditions. Our employees around the world believe in the potential of blood and cells to do even more for patients than they do today. **TerumoBCT.com**

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