Mirasol® Pathogen Reduction Technology (PRT) System PREPAReS Clinical Study

TERUMO BLOOD AND CELL TECHNOLOGIES

PREPAReS clinical study supports the safety and efficacy of Mirasol-treated platelets.

Introduction

- The Pathogen Reduction Evaluation and Predictive Analytical Rating Score (PREPAReS)* study is the **most comprehensive Mirasol clinical study to date**. It evaluated the **clinical efficacy** of buffy-coat-derived platelets in plasma treated with Mirasol.
- PREPAReS results support the **safety and efficacy of Mirasol-treated platelets**. The efficacy results demonstrated that Mirasol pathogen-reduced platelets were non-inferior to untreated platelets, suggesting that **no clinical difference exists** between the two products.

Objectives

To assess noninferiority of Mirasol-treated platelet transfusions as compared to untreated platelet transfusions.

Background and Design

- Sponsored and coordinated by Sanquin with principal investigator Jean-Louis Kerkhoffs, MD, PhD.
- Initiated in 2009 and conducted at 10 hospitals with 567 transfusion episodes and 469 patients in Canada, Norway and the Netherlands.
- Designed as a randomized, multicenter, noninferiority study using a parallel arm design with one-to-one randomization.
  - Control arm = Platelet concentrates in plasma
  - Intervention arm = Platelet concentrates in plasma, Mirasol-treated
- Study population consisted of hemato-oncological patients with thrombocytopenia.
- Primary endpoint was to evaluate the proportion of patients with bleeding events at grades 2, 3 or 4 on the World Health Organization (WHO) bleeding scale.

Results

- **Four hundred sixty-nine unique patients** were randomized to 567 transfusion episodes between November 2010 and April 2016.
- **The intention-to-treat (ITT) analysis** allowed for comparison of the treatment groups that included all patients as originally allocated after randomization. It accepted that noncompliance and protocol deviations are likely to occur in actual clinical practice and hence represented how an intervention functions in a real-world setting.
- **The primary endpoint was met** per the intention-to-treat (ITT) analysis.
- Mirasol-treated platelets in plasma are **noninferior** to untreated platelets in plasma when comparing the percentage of patients with bleeding events ≥ WHO grade 2 bleeding† (51% versus 54% of the transfusion treatment periods in the control versus intervention arm) in the ITT population.
- **No difference** was observed in patients with WHO bleeding grade 3 (2% for the control arm and the intervention arm) or grade 4 (2% for the control arm and the intervention arm) in the ITT population.
- Patients in the **intervention arm did not bleed more or longer** than those in the control arm.

Conclusion and Implications

- Mirasol-treated platelets in plasma are **noninferior** to untreated platelets in plasma when comparing the percentage of patients with WHO grade 2, 3 or 4 bleeding events in the ITT population.
- There was **no statistically significant difference in the rate** of WHO grade 2, 3 or 4 bleeding between Mirasol-treated and untreated platelets in the ITT analysis.
- Mirasol-treated platelets are capable of **supporting hemostasis** in patients.
- The PREPAReS clinical trial met the prespecified primary endpoint and **supports the safety and efficacy** of Mirasol pathogen-reduced platelets in clinical use.

RESULTS
Randomized trial, 567 transfusions and
469 patients in 3 countries from 2010 to 2016

CONTROL	MIRASOL
n = 279	n = 277
Platelets stored in plasma	Pathogen-reduced platelets
WHO bleeding grade 2, 3 or 4: 51% (ITT analysis)	**WHO bleeding grade 2, 3 or 4: 54% (ITT analysis)**

Read the complete study results here:
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. doi: 10.1182/*blood*-2018-02-831289.

*While it is one of the largest and most comprehensive, the PREPAReS trial is just one of many studies and trials that demonstrate the safety and efficacy of Mirasol.

†Difference: 3 percentage points, 95% CI (-6 to 11), p-value for noninferiority 0.012

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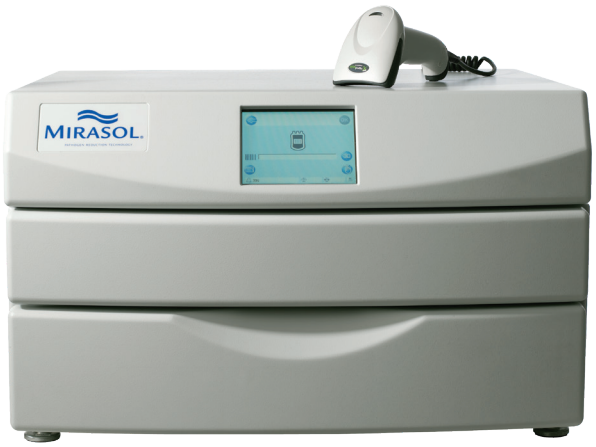

For more information about PREPAReS, contact your Terumo Blood and Cell Technologies representative.

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