Neutrolin®, A Catheter Lock Solution (CLS) With No Reported Human Resistance, Significantly Reduces The Rates Of Infection And Thrombosis In Hemodialysis Patients Enrolled In A Post-Approval Surveillance Study

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OBJECTIVES

Catheter Related Bloodstream Infections (CRBSIs) and **thrombosis** are major complications in hemodialysis (HD) patients.[1, 3] Dialysis Outcomes and Practice Pattern Study (DOPPS) data emphasized that 30-50% of HD patients develop infection over a 3-6 month period. The incidence of HD catheter thrombosis is as high as 46%.[5,6,7] HD patients with a catheter have a hazard ratio of death of 2.5 compared to HD patients with AV fistula and hospitalization for vascular access related infection in patients with a catheter are 12 times more common that for patients with AV fistula.[8] Therefore, in patients who require a central venous catheter (CVC) there is a strong imperative to eliminate catheter associated infection and thrombosis.

The objective of this study is to evaluate the use of Neutrolin®, a novel CLS comprised of taurolidine 1.35%, citrate 3.5% and heparin 1000 units/mL in reducing infection and thrombosis in HD patients.

METHODS

Study Design: post-approval surveillance program

Primary Outcome Measures:
- Number of catheter related blood stream infections (CRBSIs per 1000 CVC days)
- Number of premature CVC removals due to infection and/or thrombosis

Secondary Outcome Measures: biofilm formation in the CVCs

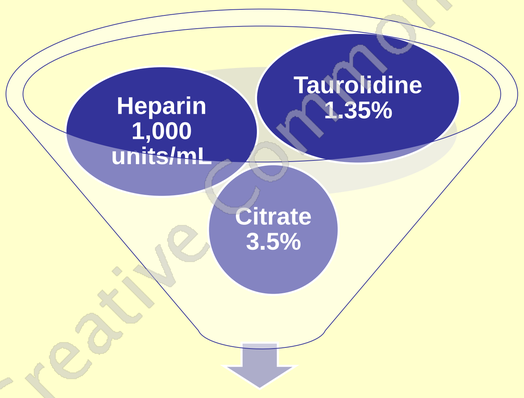
Other Outcome Measures: economic effects derived from using Neutrolin® and effectiveness in the high risk groups (e.g. diabetic patients)

Clinical Monitoring: vital signs, blood count (CBC), catheter blood flow (Qb) and urea reduction rate (URR), Kt/V, blood cultures if an infection is suspected

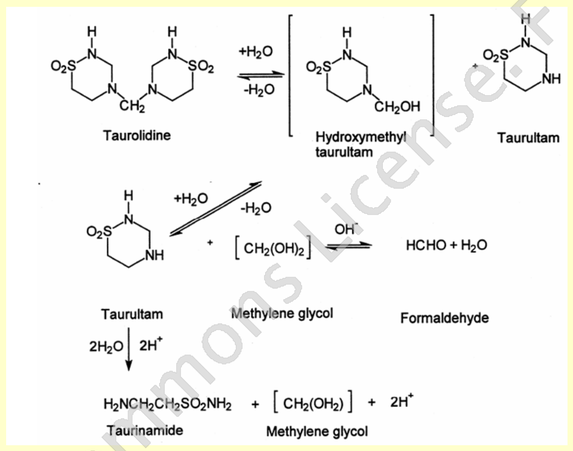
Patient Eligibility: all ages and both genders

Inclusion Criteria for Data Analysis:
- Hemodialysis patients with a new tunneled central venous catheter inserted
- Patients who were not recently hospitalized (within the last 6 months) due to CRBSIs or thrombosis in an acute care hospital or catheter clinic settings

Intervention and Duration:
Patients received Neutrolin® 2~3 times per week and followed until either the catheter fails due to clotting or CRBSIs, or it is removed due to fistula maturation.
The duration of this program is 18 months.



Taurolidine has a Dual Mechanism of Action



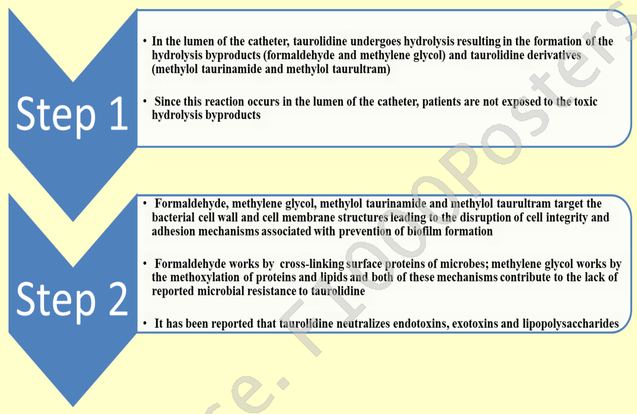


Table #1
The comparison of Neutrolin® Results to Published Benchmark Data

	Benchmark per 1000 catheter days	NUMP data per 1000 catheter days	% Reduction with Neutrolin®
Infection	3.5 [1,2,3,7]	0.14	96%
Thrombosis	2-3 [5,6]	0.09	96.4%

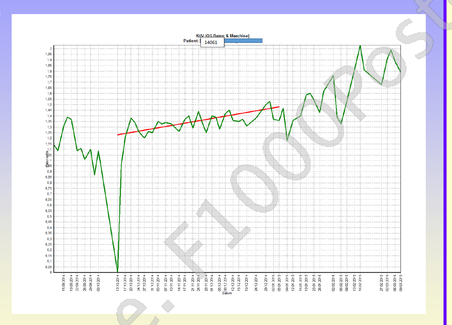
RESULTS

Patient Population: 120 hemodialysis patients (64 Male and 56 Female) at 12 dialysis centers in Germany (January 2014 to March 2015)

Hemodialysis Treatment Sessions: 9065 dialysis sessions over 15 month period for a total of 21151 hemodialysis catheter days

Primary Endpoints:
- Infection: 3 per 21151 hemodialysis catheter days
- Thrombosis: 2 per 21151 hemodialysis catheter days
- Rate of Infection with Neutrolin® Therapy: 0.14 per 1000 catheter days
- Rate of Thrombosis with Neutrolin® Therapy: 0.09 per 1000 catheter days

Case report: observation Kt/V data for one of the patients participating in the NUMP program

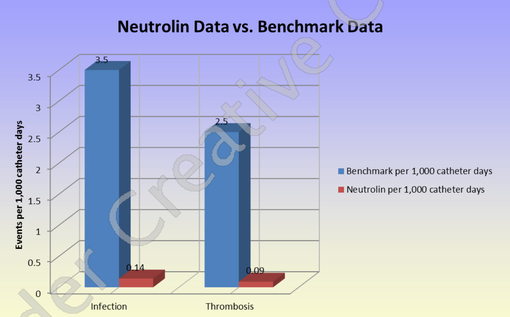


Safety:
No significant adverse drug reactions that led to the discontinuation of Neutrolin ® use were reported. Two patients experienced occasional transient dysgeusia which was not associated with any consequences.

CONCLUSIONS

Monitoring the routine use of Neutrolin®, a novel catheter lock solution, in hemodialysis patients with tunneled central venous catheter (CVC)

- The results of our study support the use of an antimicrobial CLS, Neutrolin®, in reducing CVC related complications of infection and thrombosis in HD patients
- To confirm and further expand the results of the present study, our plan is to continue to monitor and report the rates of infection and thrombosis for a total of 200 patients that are being enrolled in NUMP program



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