OBJECTIVES

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Patients
Acute PE with RV/LV ratio ≥0.9
(n= 101; 17 centers)

Objectives
Evaluate the optimal duration and dose of Acoustic Pulse Thrombolysis™ (APT) treatment using rtPA administered via the EKOS® system:

- Efficacy - Change in RV/LV ratio on CTA at 48hrs
- Safety – As measured by major bleeding within 72hrs

Randomization

<table>
<thead>
<tr>
<th>Cohort 1</th>
<th>Cohort 2</th>
<th>Cohort 3</th>
<th>Cohort 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 Patients</td>
<td>26 Patients</td>
<td>27 Patients</td>
<td>18 Patients</td>
</tr>
<tr>
<td>2 (h) EKOS®</td>
<td>4 (h) EKOS®</td>
<td>6 (h) EKOS®</td>
<td>6 (h) EKOS®</td>
</tr>
<tr>
<td>4/8 mg rtPA*</td>
<td>4/8 mg rtPA*</td>
<td>6/12 mg rtPA*</td>
<td>12/24 mg rtPA*</td>
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Methods

- Anticoagulation therapy using heparin
- Acoustic Pulse Thrombolysis™ treatment using EKOS® – following duration and dosage of randomly assigned study cohort
- Follow up at 48hrs post treatment start with CTA

1 - Victor Tapson1 Pulmonary / Critical Care Division, Cedars-Sinai Medical Center, Los Angeles, CA
2 - Gregory Piazza2, Samuel Z. Goldhaber2 Cardiovascular Division, Brigham and Women’s Hospital, Harvard University, Boston MA
3 - Keith Sterling3 Cardiovascular & Interventional Radiology, Inova Alexandria Hospital, Alexandria, VA
4 - Kenneth Ouriel4 Syntactx, NY, NY
5 - Ping-Yu Liu5 Fred Hutchinson Cancer Center, Seattle, WA

* Total mg rtPA: one/two catheters
Key Results

Acute PE patients treated with EKOS® showed the following improvements:

- Significant reduction in RV/LV ratios in all cohorts at 48 hours post initiation of procedure.
- RV/LV ratio reduced by 24% (P<0.0001) for the two-hour cohort using only 4mg of r-tPA per catheter.
- All cohorts had zero to very low bleeding rates.¹

**CONCLUSION**

The EKOS® system’s very-low-dose and short-duration regimens in the OPTALYSE PE trial appear to be as acutely effective as the regimens in other EKOS® studies (ULTIMA & SEATTLE II), pointing to a paradigm-changing approach for PE treatment. These results offer physicians a new treatment standard for proven PE clinical efficacy and safety.

¹Cohorts 1 and 3 had zero major bleeding incidents, cohort 2 had one incident and cohort 4 had two incidents (including one ICH).

* Total mg r-tPA: one/two catheters