Reviewer's report

Title: A prospective, randomized, double-blinded single-site control study comparing blood loss prevention of tranexamic acid (TXA) to epsilon aminocaproic acid (EACA) for corrective spinal surgery

Version: 2 Date: 14 October 2009

Reviewer: Jonathan A Friedman

Reviewer's report:

This protocol describes a proposed prospective blinded randomized clinical trial of the use of antifibrinolytic agents in major spinal correction surgeries. The authors hypothesize that the use of such agents will reduce intraoperative blood loss and improve ultimate outcomes.

The topic is relevant, and no study of this topic of comparable rigor exists in the literature. The protocol is concise and well-written and without major flaws. I have several minor comments:

1. More details regarding administration of the antifibrinolytic agents should be included in the standardized treatment protocol. When is the infusion started? At incision? Before? When is the infusion terminated? Is it intraoperative only?

2. I am concerned about blinding the clinicians caring for the patient in the postoperative period with respect to whether the patient had been administered antifibrinolytics or placebo. If the former, the clinicians suspicion for related complication such as stroke or renal failure may be higher, and this may lead to alteration in care. At a minimum, this ethical consideration merits further discussion.

3. The authors do not discuss complications of antifibrinolytics to any meaningful degree in this protocol, and they should. In the study design, the authors should specifically outline how they intend to monitor for and identify complications of the antifibrinolytics.

Furthermore, additional discussion should be added regarded the potential complications of treatment - ultimately, the decision on whether use of these agents is warranted is based not only on utility in reducing blood loss, but comparing this utility to complications of the treatment itself.