

Thrombase Aspiration in Myocardial Infarction (TASTE) Case Example: Learning from an Embedded Registry Trial

Embedding trials into health care delivery is possible. CTTI spoke with individuals from five different trials in which certain elements of the trial were embedded into clinical practice. We provide an example of one trial, the [TASTE](#) trial, below.

TRIAL OVERVIEW

- ▶ Randomized, controlled, open-labeled
- ▶ Number of sites: ~29 (hospitals across Denmark, Sweden, and Iceland)
- ▶ Number of patients enrolled: 7244
- ▶ Ages eligible for study: Adult, Older Adult
- ▶ Intervention: Device (thrombus aspiration vs catheter)
- ▶ Primary outcome/endpoint: all-cause mortality [Time Frame: 30 days]
 - Death from any cause is registered via national registries during the first 30 days after study inclusion.

EMBEDDED TRIAL ELEMENTS

- ▶ *Patient Identification and Randomization:* Identified, randomized, and followed patients via national registry database¹
- ▶ *Data Acquisition:* Aligned trial outcomes and endpoints to data captured within routine care and registry database (appreciating the level of structured data existing and needed)
- ▶ *Evidence Integration:* Results of a diverse, representative population made available in close to real time and rapidly translated into clinical practice

WORDS OF WISDOM

- ▶ Think through the clinical process of patients.
- ▶ Do not burden sites with extra visits. Make it simple on the investigators. Use only what's already used in routine clinical care.
- ▶ Clearly communicate to patients what is expected of them and what they're accepting to do.

- Patients should have the right to be offered randomization. If you don't get exposed to or offered randomization for a trial, that's a limitation of care.

	CHALLENGES	SOLUTIONS
Technology Infrastructure	Different legal entities and regulations required having a separate database for research purposes from that created for everyday healthcare or registry purposes	In subsequent studies, extracted registry data to feed into electronic case report forms (CRF), recognizing that the CRFs were trial specific
Data	A tension existed between outcomes that align with clinical care, such as all-cause mortality, and the need for more complex outcomes to answer specific research questions (and was adjudication needed)	Monitoring and adjudication were done as part of the regular registry validation process. Consent forms were monitored separately. There was no adjudication of events. ¹
Culture	Some physicians expressed a lack of comfort with randomization as they are used to deciding themselves what is best for their patients	Time was invested to educate hesitant physicians about research and the value of basing decisions on evidence derived from randomization
Process	Regulators were hesitant to accept cluster randomizations	Collected individual consent forms and did not cluster randomize

REFERENCES:

1. Wachtell, S. et. al. Novel Trial Designs: Lessons Learned from Thrombus Aspiration During ST-Segment Elevation Myocardial Infarction in Scandinavia (TASTE) Trial. Curr Cardiol Rep. 2016 Jan;18(1):11. doi: 10.1007/s11886-015-0677-6.