INTACT-AD
International TransAtlantic Cooperative Trial – On Aortic Dissection Protocol
www.intactadtrial.org
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Conflicts
- None

Patient Population
- INTACT-AD will be a pragmatic, international, multicenter, prospective, randomized, controlled, open-label clinical trial, with enrollment and end points evaluated through comprehensive national registries
- All baseline and procedural data are entered directly into online registry
- Sample size = 1200
- Timing of intervention: within 15-90 days of index event

INCLUSION CRITERIA
- Age >18 years
- Ability to provide written informed consent and comply with the protocol
- Stanford type B aortic dissection, WITHOUT acute complications
Exclusion Criteria

- Acute end-organ ischemia (renal, mesenteric, or extremity ischemia)
- Patients with prior TEVAR
- Tear within 15 mm of left carotid artery
- Rupture of the aorta or extra-luminal collection of blood
- Complete thrombosis of the false lumen
- Connective tissue disorder (e.g., Marfan syndrome)
- Ongoing systemic infection
- Pregnant or planning to become pregnant in the next 3 months
- Life expectancy related to non-aortic conditions < 1 year

Proposed Sub-Studies

- CORE IMAGING STUDY
- COST BENEFIT & COST EFFECTIVENESS STUDY-Separate Application

Objectives of Imaging Study

- To study the natural history of uncomplicated TBAD treated with TEVAR or MT alone over time
- Identify the radiologic characteristics that are related to later aortic expansion, development of acute complications (rupture and malperfusion syndrome) or death

FEASIBILITY

- Of 130 surveyed centers, 114 replied yielding a response rate 89%, including 78 centers in the US, 4 in Canada, 30 in EU, 1 in Turkey and 1 in Israel.
- Eighty-seven respondents were vascular surgeons, 18 cardiac surgeons, 10 cardiologists, and 2 radiologists.
- All centers indicated NIH/FDA or device trial experience
- If we enroll 5 patients/center/year → complete enrollment in less than 2.5 years

Is there clinical equipoise in your center regarding the appropriate management of uncomplicated type B aortic dissection?

- Yes (90.5%)
- No (11.1%)

Do you routinely stent uncomplicated type B aortic dissection?

- Yes (7.9%)
- No (37.7%)
- Left untried (54.4%)
Do you think that the composite endpoint is appropriate to change practice?

![Pie chart showing distribution of responses to the question.]

Estimate the likely enrollment at your Clinical Center of eligible Type B aortic dissection patients PER YEAR for three years.

![Line graph showing enrollment over three years.]

Number of uncomplicated Type B aortic dissection patients you treated in 2014.

![Scatter plot showing distribution of patient data.]

Trial Organization

- Clinical Coordinating Center: Columbia-Surgery
- Data Coordinating Center: Cardiovascular Research Foundation and Mailman School of Public Health
- Statistical Analysis Center: Mailman School of Public Health
- VQI leadership
- IRAD leadership
- Steering Committee (4 VS, 4 CT, 1 IR)
- DSMS (1 cardiologist, 4 VS)
- CEC

Conclusions

- Type B aortic dissection is common and carries a significant in-hospital mortality with long term morbidity and mortality
- Current guidelines recommend medical therapy as first line therapy in uncomplicated TBAD
- There appears to be clinical equipoise regarding the long-term benefit of TEVAR in the setting of uncomplicated TBAD
- Leveraging the data collection system (IRAD and VQI) already in place from two ongoing registries will increase efficiency and potentially lower cost
- Timely trial, widespread interest