Minimally Invasive Staged Segmental Artery Coil Embolization (MIS²ACE) to improve collateral circulation to the spinal cord: from preclinical testing to the PAPA-ARTIS RCT

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spinal cord collateral circulation

BASICS
In patients with TAAA, most intercostal and lumbar arteries are occluded and spinal cord perfusion depends on an eminent collateral network.
During and after repair, the spinal cord blood supply may crucially depend on collateral arteries.

Presence of collateral arteries predicted stable MEPs in 97% of patients.

Incidence of SCI in patients in which a collateral network could not be visualized was 38%!
100 pts, 8.0 ± 2.6 SA pairs sacrificed: paraplegia rate: 2% (!)

not explained by Adamkiewicz’s Artery!
SPINAL CORD ARTERIOLAR NETWORK
Segmental Artery Occlusion

KEY EXPERIMENTAL EVIDENCE
cranial

Lumbar Paraspinal Network*

* ASA → *

Native

5 days after TAASA occlusion
clinical implication:
THE STAGED REPAIR
Total segmental artery occlusion: regeneration of arterial perfusion within 5 days

*staged = 100% recovery*

(Unplanned) extensive staged segmental artery sacrifice = 100% recovery!
> 10fold reduction in SCI rate with staged endovascular repair
new 'staging' technology:
'PRIMING' COLLATERAL REGENERATION
clinical solution:

Minimally invasive *staged* segment artery coil embolization: MIS$^2$ACE

Minimally invasive coil deployment - schematically

Coil-occluded (right) / patent SA (left)
First-in-man endovascular preconditioning of the paraspinal collateral network by segmental artery coil embolization to prevent ischemic spinal cord injury

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...several important breakthroughs relating to managing and preventing spinal cord injury have been simultaneously brought together with the MISACE technique.
Minimally Invasive Segmental Artery Coil Embolization (MISACE)

- First Stage -
1. Staged preconditioning — now clinically available
2. Staging with only 1-3 sessions in the cath lab
3. Reduced steal / clean OR field / shorter OR times
4. Reduction of type II endoleakage after endo repair
clinical evidence: THE RCT

PAPAartis
fighting spinal cord injury
Paraplegia Prevention in Aortic Aneurysm Repair by Thoracoabdominal Staging with ‘Minimally-Invasive Segmental Artery Coil-Embolization (MISACE)’: A randomized controlled multicentre open-label trial (PAPA-ARTiS)
Trial duration
- First patient in to last patient out (months): 40
- Duration of the entire trial (months): 46
- Recruitment period (months): 24

Independent radiological verification of inclusion criteria

Randomization stratified by surgery/TEVAR

Efficacy: In the control arm success is expected in 75% of patients compared to 90% in the experimental (MISACE staging) arm.

Description of the primary efficacy analysis and population: Mixed logistic regression

Sample size
- To be assessed for eligibility: n = 450
- To be assigned to the trial: n = 306
- To be analysed:
  - n = 160 (interim 1), 220 (interim 2), 275 (final)

Secondary endpoints: Analysis of binary outcomes will be analogous to the primary analysis. ICU time will be analysed with a linear mixed model. Re-operation and endoleak will be considered for the subgroups of surgery/TEVAR respectively.
1. CH: Bern
2. DE: Freiburg
3. DE: Hamburg
4. DE: Leipzig
5. FR: Bordeaux
6. FR: Lille
7. IT: Bologna
8. IT: Milan
9. NL: Maastricht
10. PL: Zabrze
11. SE: Malmö
12. SE: Örebro
13. UK: Liverpool
14. US: Houston
15. US: Philadelphia
16. DE: Munich
17. DE: Warsaw

Figure 10 - Participating centres PAPA-ARTIS (EU, Switzerland and the US). Red stars represent recruitment centres and the yellow stars represent the radiology core lab (Copenhagen, WP6) and the health economics group (Grenada, WP3).
1: Aachen
2: Bern
3: Essen
4: Freiburg
5: Hamburg (UKE)
6: Hanover (MHH)
7: Heidelberg
8: Innsbruck
9: Leipzig
10: Munich
11: Münster
12: Nuremberg
13: Vienna
14: Regensburg
... largest publicly funded RCT in aortic aneurysm repair

17 (+14) Aortic Reference Centres

prospectively collect contemporary real-world data on SCI incidence (type II, III; open + endo)

comparing ‘staged’ vs. ‘conventional’ approach

evaluating effectiveness of MISACE:
– SCI protection & endoleak type II prevention
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