

Spinal cord protection by selective spinal artery coil embolization –
update on the PAPA-ARTIS trial

PAPAartis
fighting spinal cord injury



CHRISTIAN D. ETZ

LEIPZIG

The author declares no conflict of interest

The presented work is part of the Heisenberg focus project 'Spinal Cord Protection' for Aortic Surgery funded by the German Research Foundation (DFG) and the PAPAartis RCT has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733203



Staged repair significantly reduces paraplegia rate after extensive thoracoabdominal aortic aneurysm repair

Christian D. Etz, MD, PhD,^a Stefano Zoli, MD,^a Christoph S. Mueller, MS,^a Carol A. Bodian, DrPH,^b Gabriele Di Luozzo, MD,^a Ricardo Lazala, MD,^a Konstadinos A. Plestis, MD,^a and Randall B. Griepp, MD^a

Open surgery, staged repair:
SCI reduction from 15% to 0%

Eur J Vasc Endovasc Surg (2015) 49, 248–254

Editor's Choice — The Impact of Early Pelvic and Lower Limb Reperfusion and Attentive Peri-operative Management on the Incidence of Spinal Cord Ischemia During Thoracoabdominal Aortic Aneurysm Endovascular Repair

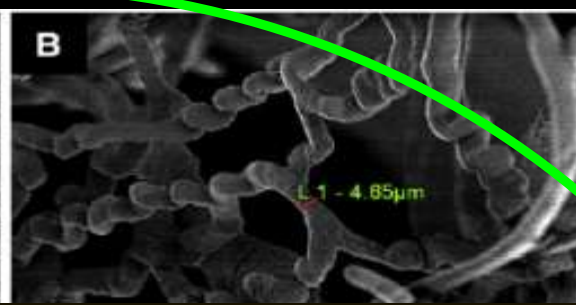
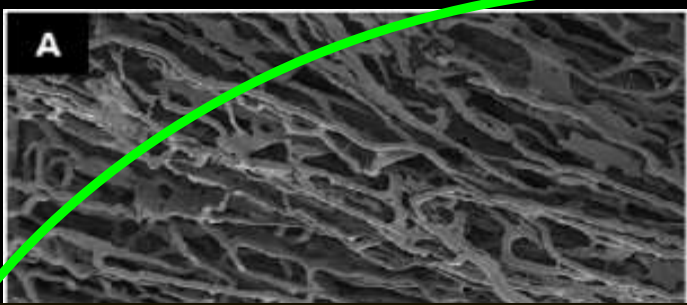
B. Maurel ^a, N. Delclaux ^a, J. Sobocinski ^a, A. Hertault ^a, T. Martin-Gonzalez ^a, M. Moussa ^a, R. Spear ^a, M. Le Roux ^a, R. Azzaoui ^a, M. Tyrrell ^b, S. Haulon ^{a,*}

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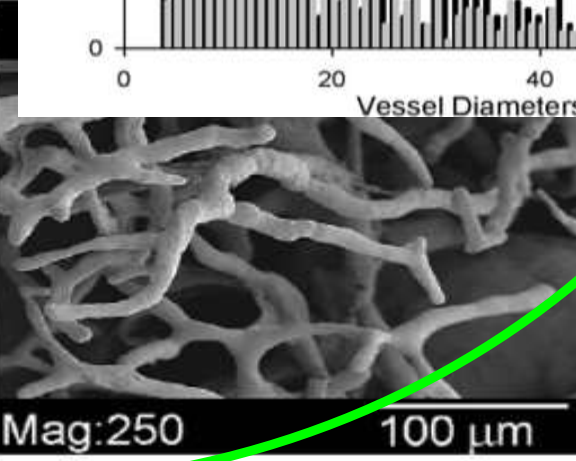
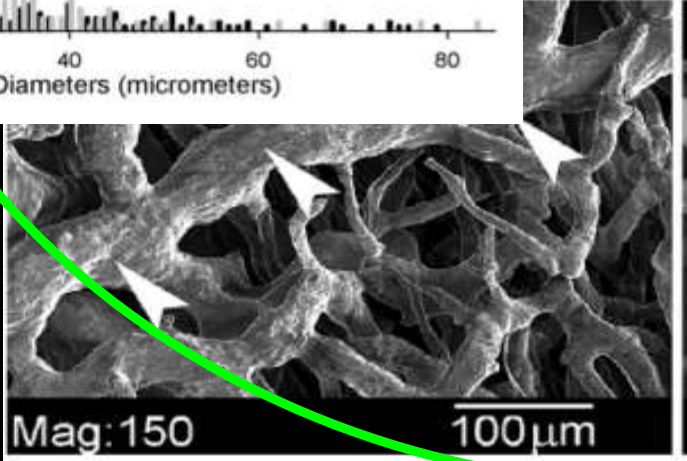
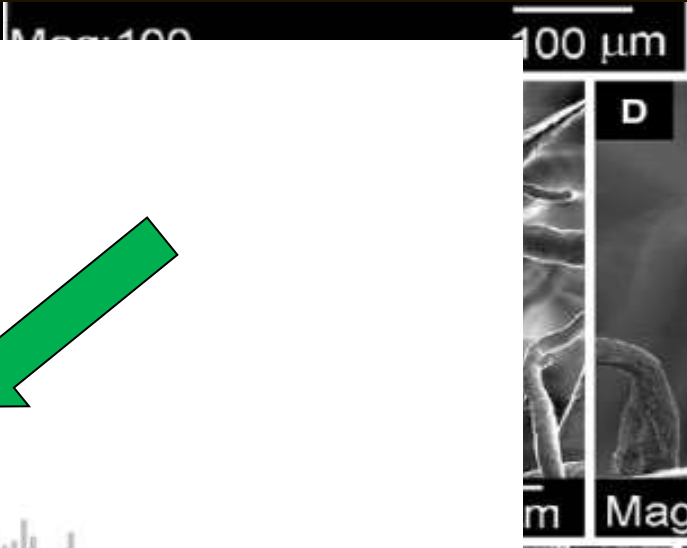
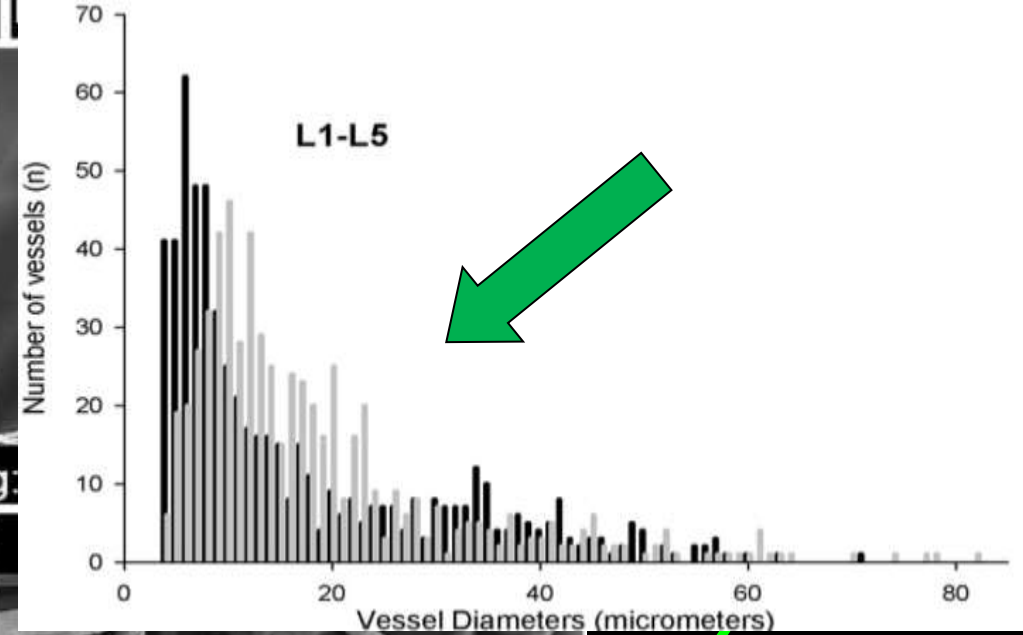
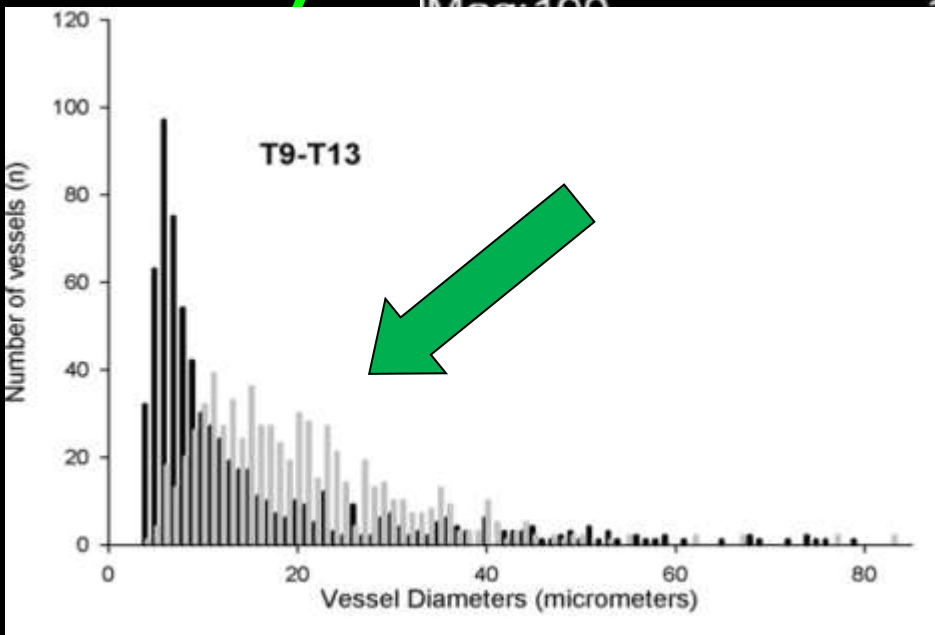
^b King's Health Partners, London, UK

Endovascular, staged Repair

SCI reduction “10fold” — from 25% to 2.4%



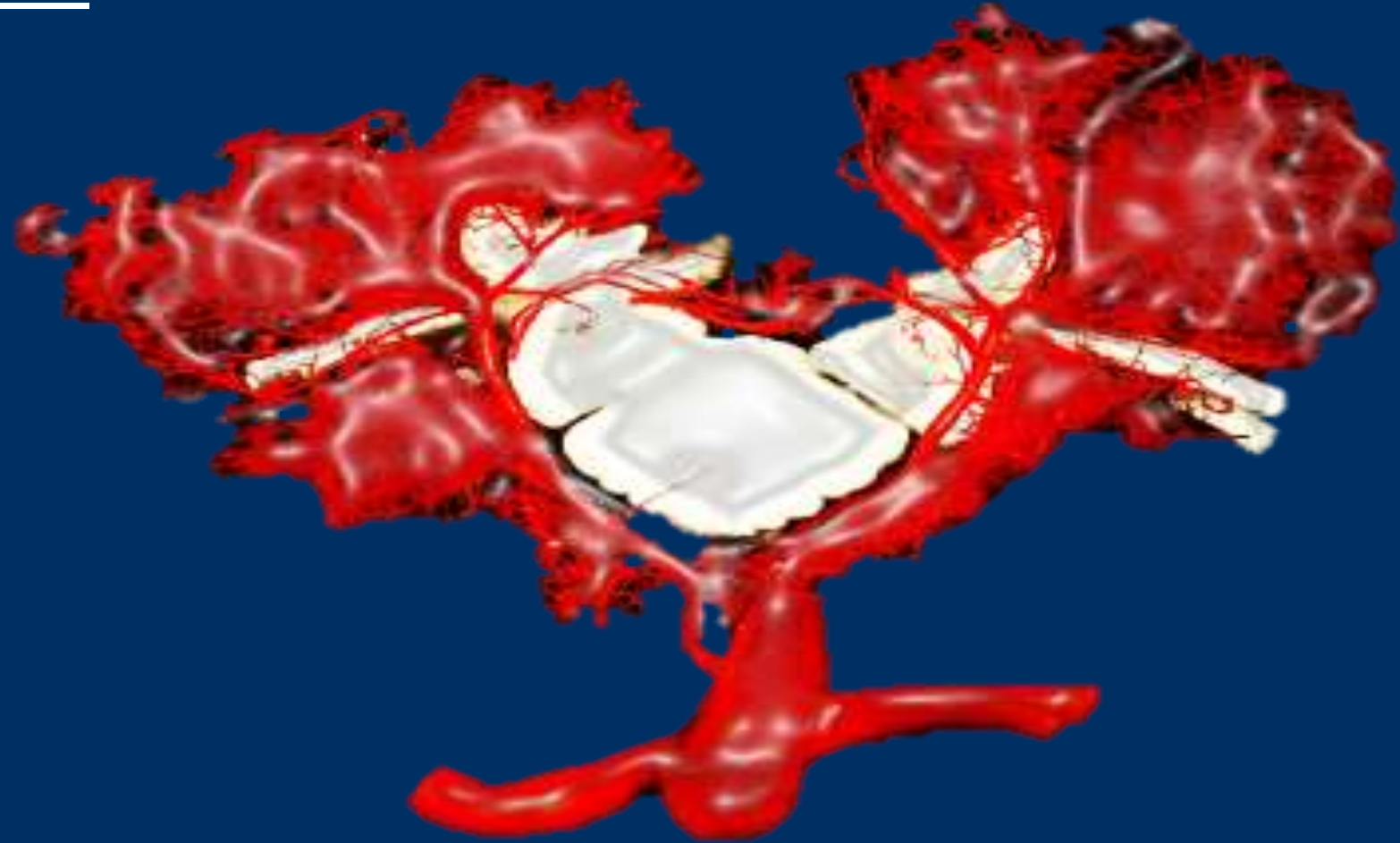
EVIDENCE OF ARTERIOGENESIS



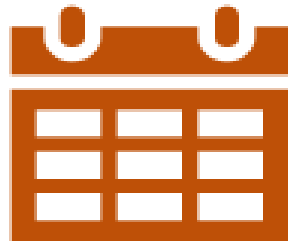
THE STAGED REPAIR

MINIMALLY INVASIVELY

MIS²ACE



PRIMING COLLATERAL REGENERATION !



5 year duration



500 participants



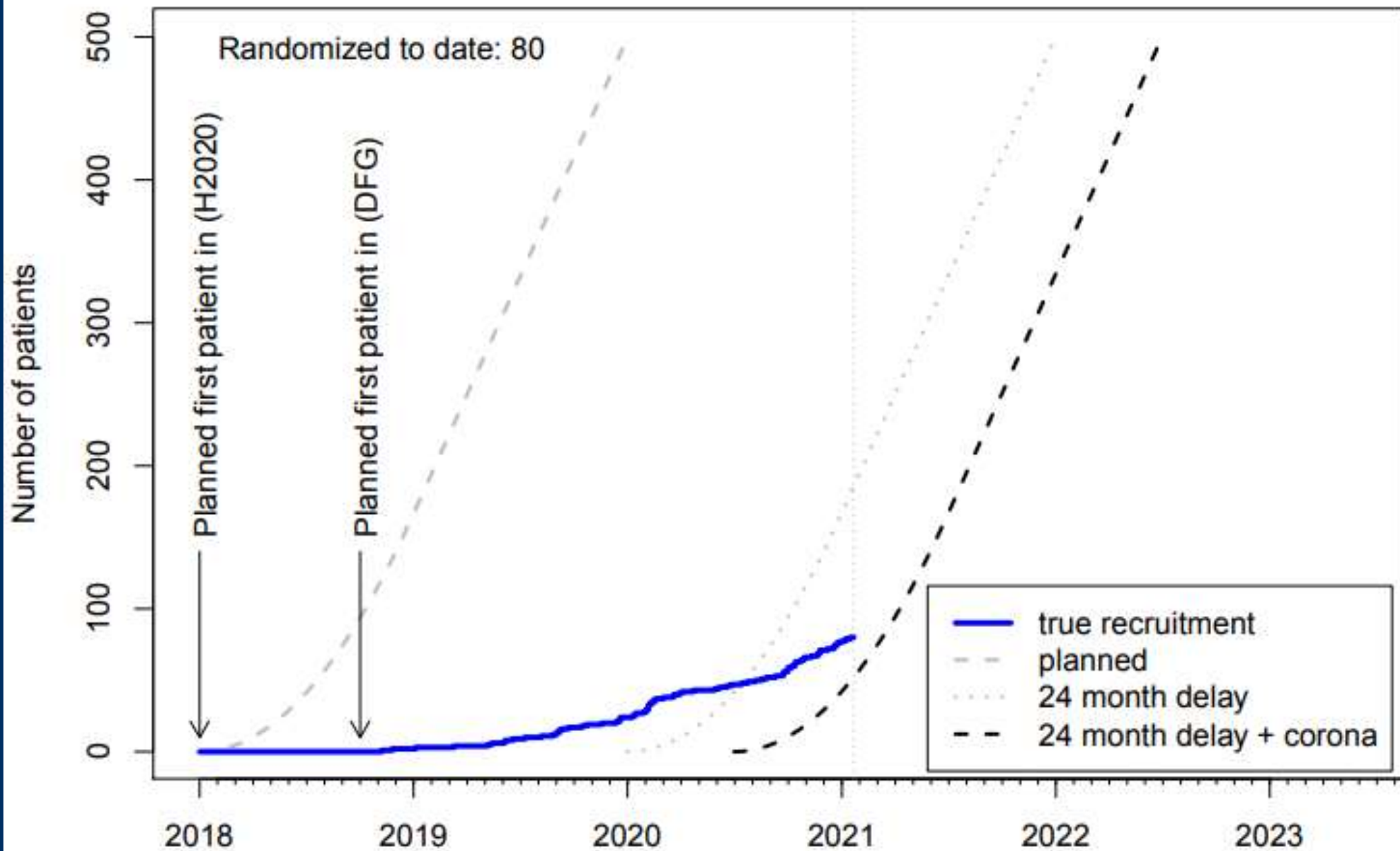
**31 recruiting sites
in 9 countries**



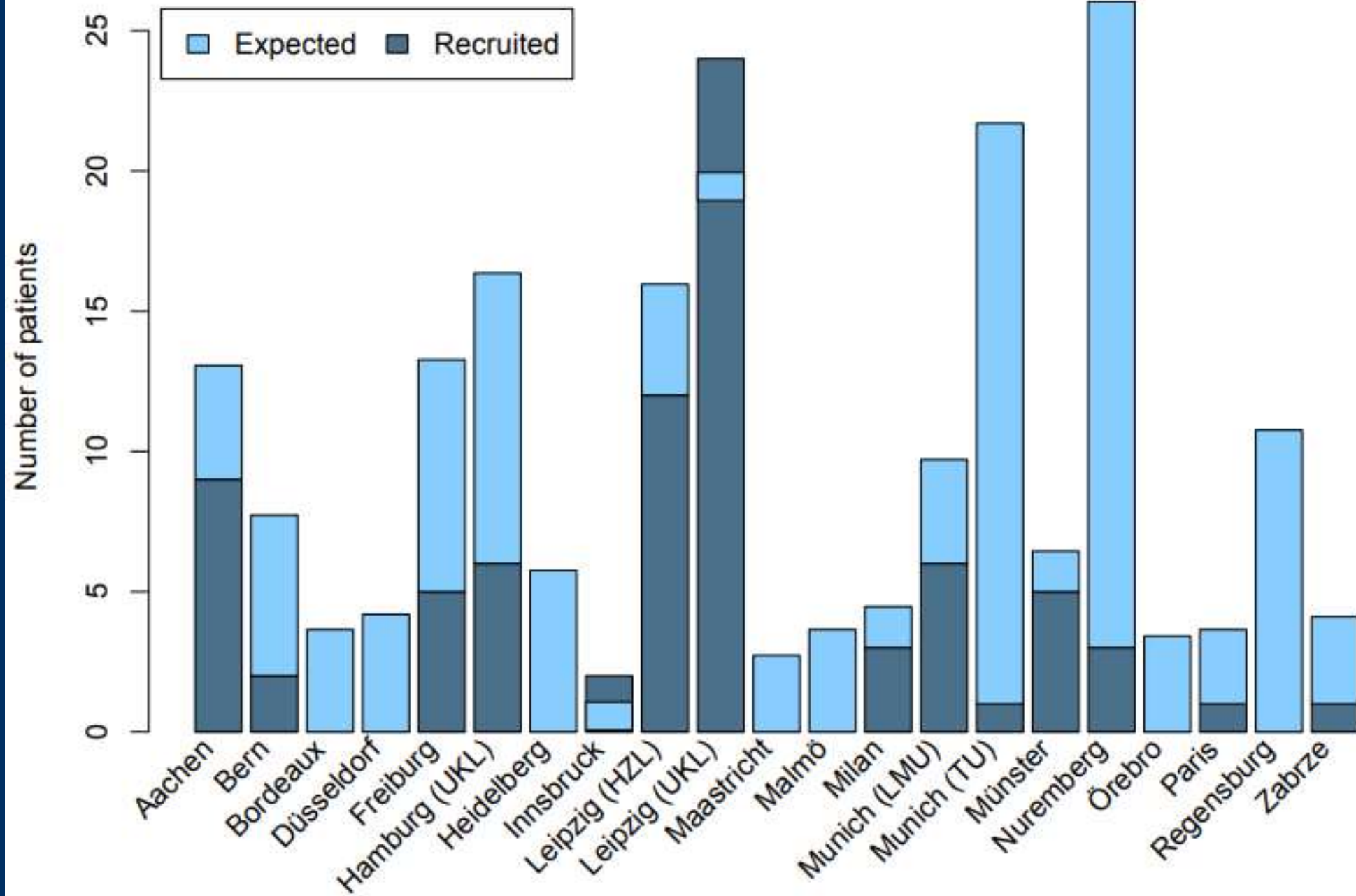
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733203 and the German Research Foundation.



Recruitment in PAPAartis (2021-01-21)



Number expected: 198, Number randomized: 80, 2021-01-21



Statistical Monitoring Report for PAPAartis

for the trial

Paraplegia Prevention in Aortic Aneurysm Repair by Thoracoabdominal Staging with "Minimally-Invasive Staged Segmental Artery Coil-Embolization": A Randomized Controlled Multicentre Trial

PAPAartis

NCT03434314

Coordinating investigator

Prof. Christian D Etz

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Biometry

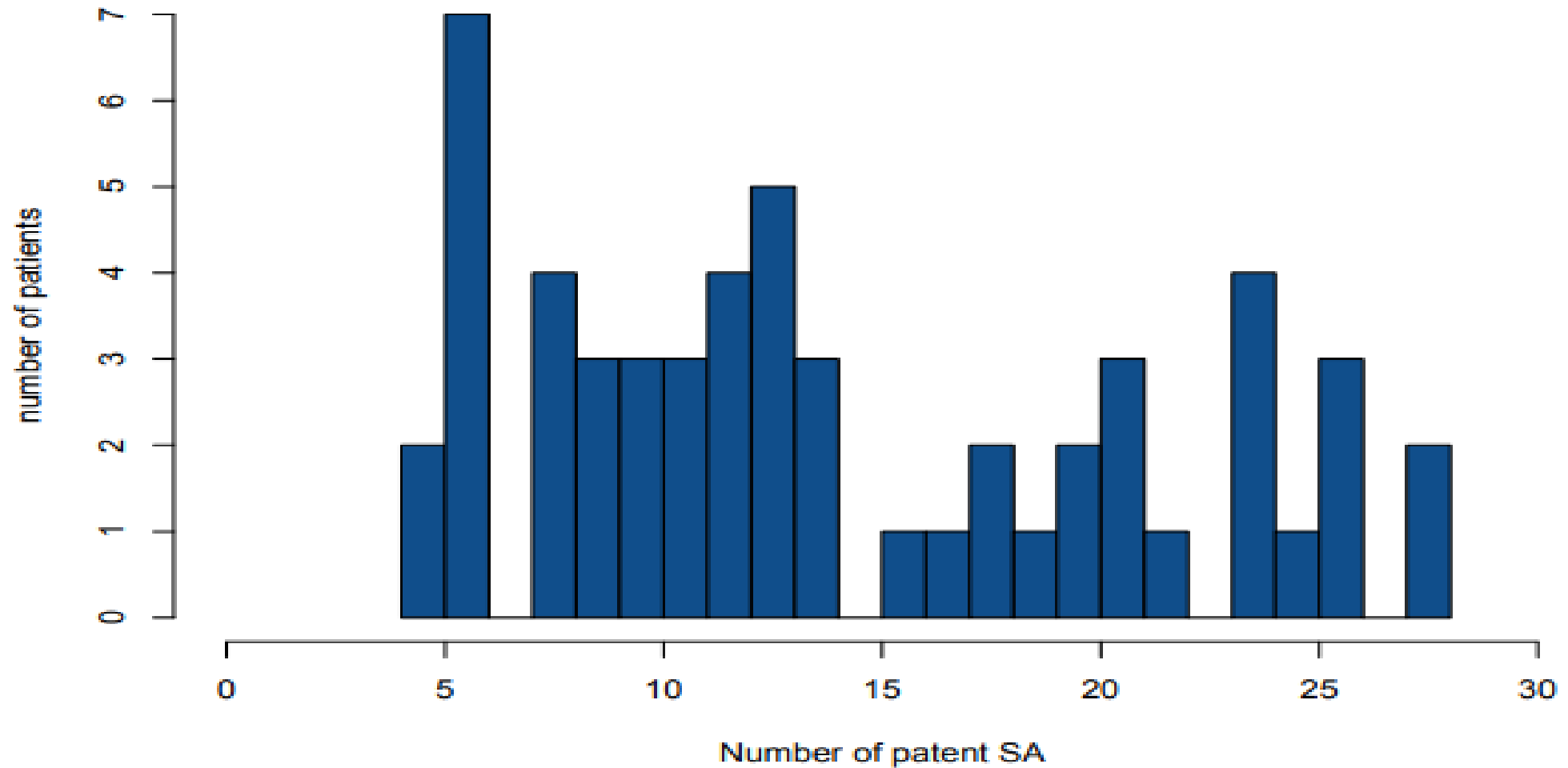
Dr. David Petroff

Clinical Trial Centre Leipzig Universitaet Leipzig

Haertelstraße 16-18, 04107 Leipzig, Germany

Date: 2020-12-15

patent segmental arteries / patient



of MIS²ACE-sessions / patient

4 MIS²ACE procedure

Table 2: Specifics of the MIS²ACE sessions. Note that inconsistencies in the database are expected until all queries have been resolved. SA=segmental arteries

	Session I	Session II	Session III
Number of patients	31	13	8
Dosis area product (Gy × cm ²)	150 ± 181	87 ± 90	86 ± 70
Duration of session (hours)	1.8 ± 1.1	2.0 ± 1.0	2.0 ± 1.2
Number of occluded SA (not pairs)	3.0 ± 2.4	3.1 ± 1.7	2.5 ± 1.2
> 7 pairs occluded	0	0	0
Number of coils/plugs	12.4 ± 12.9	14.2 ± 12.0	12.5 ± 11.1
Number of sessions terminated early	2	1	1
Number of sessions with complications	0	1	0

„Time to repair“

(time since randomization)

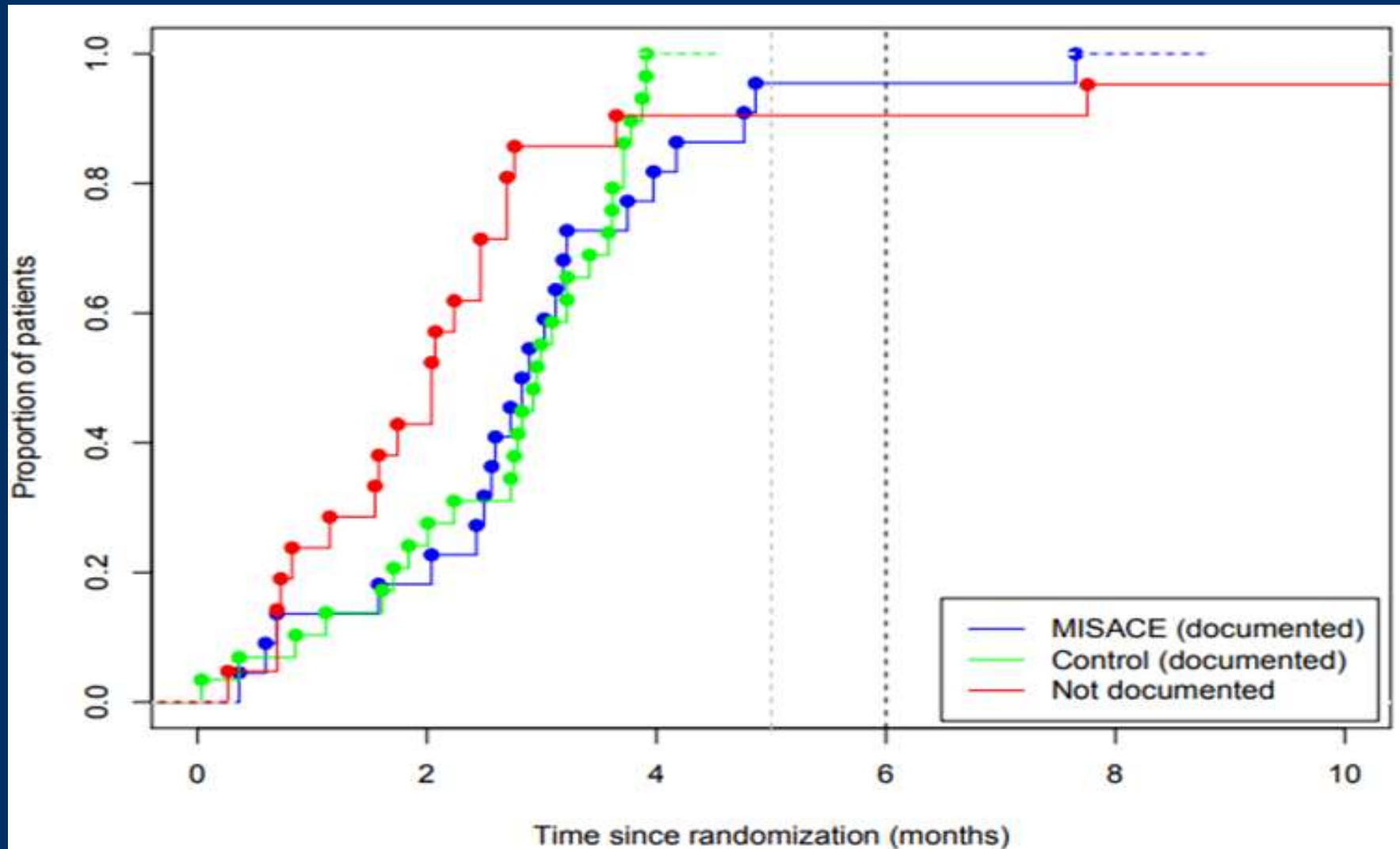


Figure 6: Time to repair or end of study. If a multiple staged repair was used, the last stage of repair is taken. For repairs not (yet) documented, the date from randomization till now is used.

Data quality and safety: high

6 Data Quality

6.1 Neurological assessments at baseline

Table 3: Completeness of neurological baseline data. Sites are considered to have provided data if a date for the CRF was entered.

	Neurological examina- tion	mRS-9Q	Symptoms (mRS-9Q)	MoCA	Barthel- Index
Aachen (n=9)	5	8	3	5	8
Bern (n=2)	2	2	2	2	2
Freiburg (n=4)	2	2	0	2	2
Hamburg (UKL) (n=6)	6	5	3	3	5
Innsbruck (n=2)	2	1	1	1	2
Leipzig (HZL) (n=12)	9	9	5	9	9
Leipzig (UKL) (n=22)	19	20	9	19	20
Milan (n=3)	3	3	2	3	3
Munich (LMU) (n=6)	3	4	1	4	4
Munich (TU) (n=1)	1	1	0	1	1
Münster (n=5)	5	5	1	5	5

7 Safety

There have been 236 adverse events (115 MIS²ACE, 121 control) from 50 patients (27 MIS²ACE, 23 control), 97 of which are serious adverse events (43 MIS²ACE, 54 control). There were 7 AEs that are possibly related to MIS²ACE, 66 possibly related to the repair and 93 related to repair.

4.2 Details of complications

- Pain, Thorax left site, after coiling TH8 left - resolved after morphin

4.3 Time between sessions

Out of 13 documented cases, the mean \pm sd time between MIS²ACE sessions 1 and 2 was 23 ± 13 days. There were 0 instances in which it was less than 5 days. Out of 7 documented cases, the time between sessions 2 and 3 was 16 ± 9 days. There were 0 instances in which it was less than 5 days.

4.4 Acute back pain

There were 1 instances of acute back pain during the MIS²ACE procedure amongst 1 patients. There were 49 documented cases *without* back pain amongst 30 patients.

4.5 Radiation

The total DAP per patient over all sessions was $207 \text{ Gy} \times \text{cm}^2$ and there were 7 patients with more than $300 \text{ Gy} \times \text{cm}^2$.¹

Figure 4: Dosis area product (DAP) over all MIS²ACE sessions per patients.

