BIOSOLVE-I
36-month results

Conclusions

- No definite or probable late or very late Scaffold Thrombosis (ST) was observed with Magmaris precursor devices in clinical trials up to 36 months
- Excellent long-term outcomes at 3 years with a low Target Lesion Failure (TLF) rate and no cardiac death or ST

Study design

Prospective, multi-center, first-in-man trial testing DREAMS (Drug-Eluting Absorbable Magnesium Scaffold).

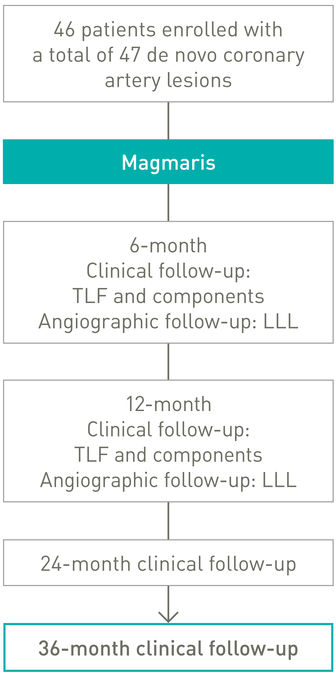
Endpoints

Primary endpoint

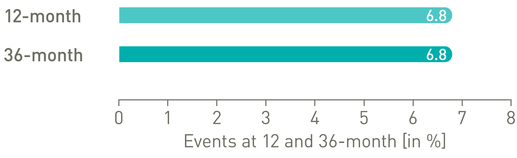
- TLF defined as a composite of cardiac death, Target-Vessel Myocardial Infarction (TV MI) and Clinically-Driven Target Lesion Revascularization (CD-TLR) at 6 and 12 months

Secondary endpoints (selected)

- Late Lumen Loss (LLL) at 6 and 12 months
- ST at 1, 24 and 36 months
- Cumulative rates of TLF at 1, 24 and 36 months



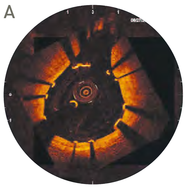
TLF



	12 months	36 months
TLF*	6.8%	6.8%
TLF components		
Cardiac death	0.0%	0.0%
TV MI	2.3%	2.3%
CD-TLR	4.5%	4.5%
ST definite or probable	0.0%	0.0%

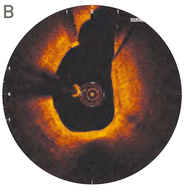
Representative optical coherence tomography after DREAMS implantation (A) and at 6 months (B) and 12 months (C)

A



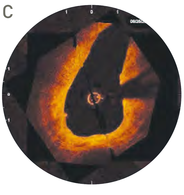
Immediately after implantation strut apposition to the vessel wall is good, with some struts covering the side branch.

B



At 6 months remnants are mostly covered and former struts over the side branch are being resorbed.

C



The change from a metallic stent-like appearance to remnants after magnesium resorption is shown.

Principal investigator

Prof. M. Haude, Lukaskrankenhaus, Neuss, Germany

Reference: Haude M, et al. Safety and performance of the drug-eluting absorbable metal scaffold (DREAMS) in patients with de novo coronary lesions: 12-month results of the prospective, multi-centre, first-in-man BIOSOLVE-I trial. Lancet. 2013; 381: 836-44.

* TLF defined as a composite of cardiac death, TV MI and CD-TLR

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