



LINCC

New data on paclitaxel in the next couple of years; what should we expect?

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Disclosure

Speaker name:

.....Dr. Eva Freisinger.....

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest.

Upcoming Trials

Trial and Sponsor	Design	Cohort	Status
<p>Acotec DCB Post Market Clinical Follow-up (FLOWER) Acotec Scientific Co., Ltd</p>	<p>Observational All-comers, prospective, multi-center, single-arm, post market clinical follow-up (PMCF); follow-up 5 years</p>	<p>Claudicants; Critical Limb Ischemia</p>	<p>Recruiting</p>
<p>Safety Assessment of Femoropopliteal Endovascular Treatment With PAclitaxel-coated Devices (SAFE-PAD) Beth Israel Deaconess Medical Center</p>	<p>Observational retrospective cohort study on claims data; median follow-up time > 5 years.</p>	<p>Claims data; Fem-pop revascularization with either DES ± DCB, BMS with DCB, or DCB alone, or non-drug-coated devices (BMS ± PTA or PTA alone).</p>	<p>Active, not recruiting</p>
<p>PTA and Drug Eluting Stents for Infrapopliteal Lesions in Critical Limb Ischemia (PADI) Netherlands Society for Interventional Radiology</p>	<p>Interventional RCT Phase 2, Phase 3 follow-up death: 1 year; amputation up to 10 years</p>	<p>Critical Limb Ischemia; Treatment of BTK arterial lesions with PTA and DES vs. PTA only</p>	<p>Active, not recruiting</p>

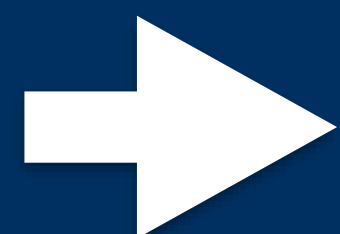
What is next?

- **focus on specific patient cohorts**

e.g. chronic kidney disease, elderly people, very young patients, sex differences,...

- **focus on specific vascular pathologies**

e.g. severely calcified lesions, BTK, long lesion,...



moving beyond mortality towards efficacy

What is next?

- **new technologies of drug application**

e.g. bioabsorbable DES (SFA)

direct drug injection into arterial wall (Mercator Bullfrog)

BULLFROG
MICRO-INFUSION DEVICE

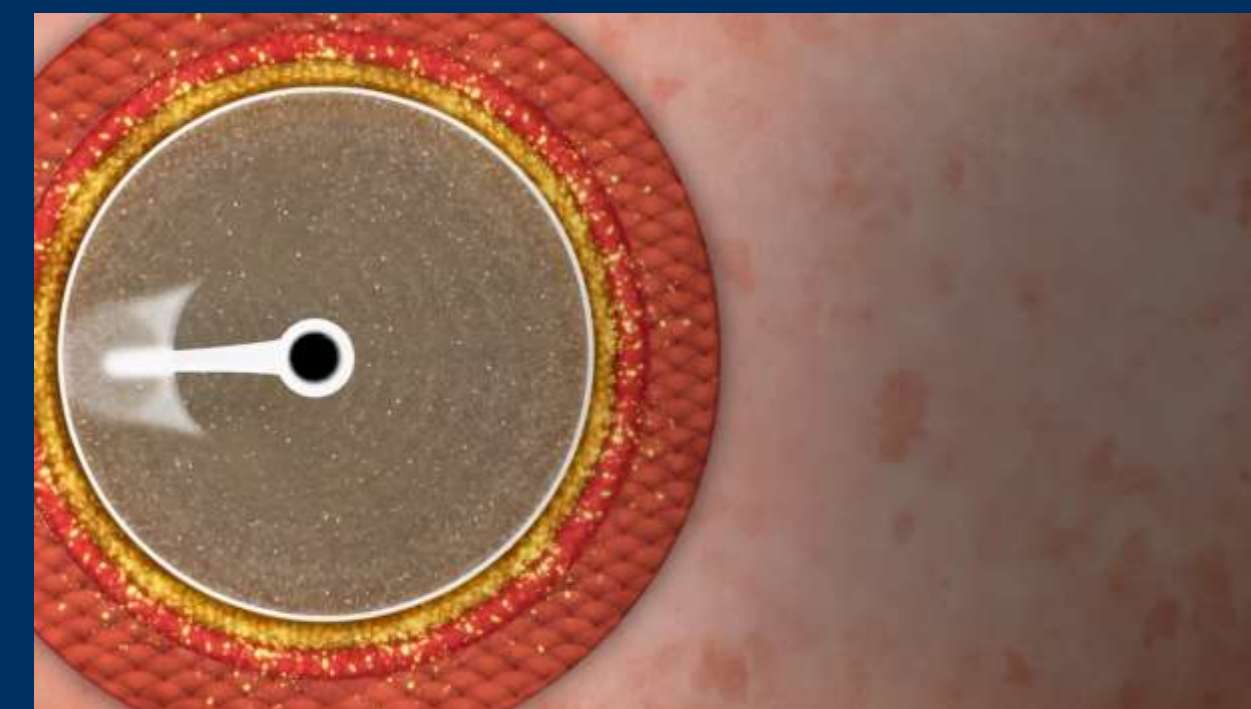
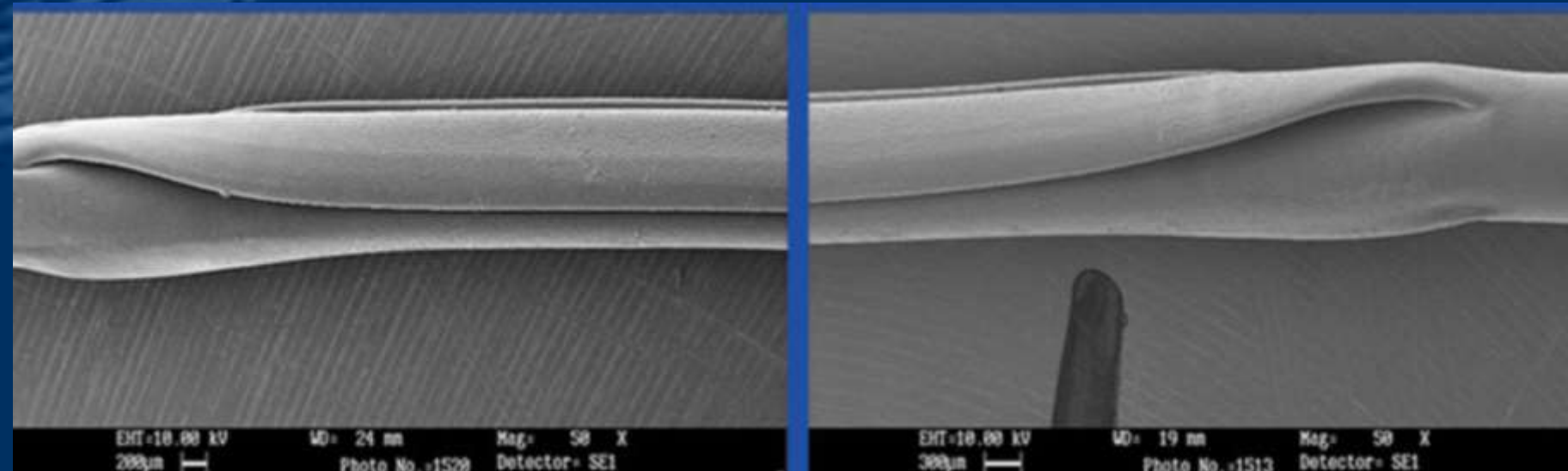


Trial and Sponsor	Design	Cohort	Status
Prevention of Restenosis Following Revascularization Celgene Corporation	Interventional RCT prospective, randomised trial Phase 2	PAD with SFA intervention EVR + Nanoparticle Paclitaxel (albumin-bound) i.a. + i.v. vs. EVR alone	Terminated

What is next?

- **substances alternative to paclitaxel**
e.g. Sirolimus DCB/DES
bioabsorbable Everolimus DES (BTK)

MagicTouch SIROLIMUS COATED BALLOON CATHETER

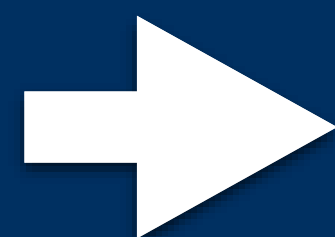


- TECHNOLOGY**
An innovative proprietary Nanolute technology providing better bioavailability of SIROLIMUS
- DRUG**
Sirolimus: A drug with proven safety profile
- COATING**
Unique coating technology leads to 100% balloon surface coating
- CARRIER**
A biocompatible phospholipid drug carrier improving the adhesion property of Sirolimus

What is next?

Trial and Sponsor	Design	Cohort	Status
Intima Versus Adventitia Drug Delivery to Elucidate Mechanisms of Restenosis: Magnetic Resonance Imaging (INVADER MRI) University of California, San Francisco	Interventional RCT prospective, multi-center, randomised trial Phase 4	PAD with SFA intervention. POBA + Dexamethasone i.a. vs. POBA + Paclitaxel DCB	Recruiting
The DESappear Study: Drug Eluting Scaffold (DESappear) Elixir Medical Corporation	Interventional study prospective, mutli-center, single arm study	PAD with SFA intervention Akesys Prava Sirolimus eluting bioresorbable scaffold system	Active, not recruiting
Safety and Feasibility of Surmodics SUNDANCE™ Drug Coated Balloon (SWING) SurModics, Inc.	Interventional study prospective, mutli-center, single arm study	PAD with BTK intervention SUNDANCE™ Drug Coated Balloon (sirolimus)	Recruiting
BRight DCB First-in-Human Study Biotronik CRC Inc.	Interventional study prospective, single arm study	PAD with SFA intervention BRight DCB (sirolimus)	Not yet recruiting

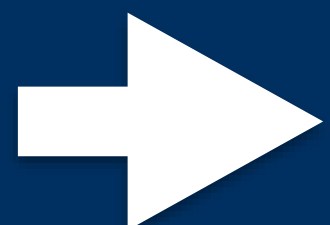
<https://clinicaltrials.gov/ct2/results?term=lower+extremity+artery+disease%2C+paclitaxel&cond=Peripheral+Artery+Disease> accessed 05. Jan. 2021



comparative analyses

What have we learned?

- post-market surveillance of medical products



***accompanying national and international registries
linked with official death records***