SWedish Drug-Elution trial in Peripheral Arterial Disease
Disclosure

Speaker name:

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
What is a proper outcome measure for PAD treatment

Late lumen loss?
Primary patency?
Target lesion revascularisation?
Binary restenosis?
What is a proper outcome measure for PAD treatment

Late lumen loss?
Primary patency?
Target lesion revascularisation?
Binary restenosis?

SURROGATES!
Intermittent claudication

Improved quality of life

Critical limb ischemia

Avoid amputation
Randomized Studies (RCT)

Registries
A new clinical trial design; The *Register* based randomized trial (RRCT)

Combining an established registry with an online randomization function

Allows large clinical trials

The *Swedvasc* registry records 3000 infrainguinal endovascular procedures/year
Inclusion criteria
Symptomatic PAD caused by >50% stenosis or occlusion of infrainguinal arteries and eligible for endovascular treatment

Exclusion criteria
Acute thromboembolic
Infrainguinal aneurysm
Patients planned for infrainguinal endovascular procedure

Critical ischemia
SWEDPAD 1

Intermittent claudication
SWEDPAD 2
Patients planned for infrainguinal endovascular procedure

Critical ischemia
SWEDEPAD 2

Randomization in registry

DE
No-DE

Intermittent claudication
SWEDEPAD 2

Randomization in registry

DE
No-DE
Patients planned for infrainguinal endovascular procedure

Critical ischemia SWEDEPAD 2

Randomization in registry

DE

No-DE

Intermittent claudication SWEDEPAD 2

Randomization in registry

DE

No-DE

Register follow-up (one month, one year)

Additional follow-up (letter/phone call, healthcare registries) (Three and five years)
Primary endpoints

Critical Ischemia
- Amputation rate

Intermittent Claudication
- health-related quality of life after one year (VascuQol 6)
Secondary endpoints

**Critical Ischemia**
- Survival after one year and long-term
- Amputation free survival.
- Freedom from target lesion revascularisation (TLR) after one year.
- Time to target lesion revascularisation (TLR) during follow-up.
- Patency, defined as freedom from binary restenosis, a reduction in lumen diameter ≥50% in patients assessed with duplex ultrasound after one month and after one year.
- Improvement in clinical symptoms, assessed with the Rutherford classification at one month and one year. Particularly changes from Rutherford categories 4, 5 and 6 to lower categories.
- Ankle-brachial index (ABI) after one month and after one year.
- Health related quality of life, assessed with VascuQol-6, a disease-specific health –related quality of life instrument in PAD, after one month and one year, and during long-term follow up.
- Survival after one year and during long-term follow-up.
- Health-economic assessment after one year and during long-term follow-up (only certain centres).

**Intermittent Claudication**
- Survival after one year and long-term
- Amputation free survival.
- Freedom from target lesion revascularisation (TLR) after one year.
- Time to target lesion revascularisation (TLR) during follow-up.
- Patency defined as freedom from binary restenosis, a reduction in lumen diameter ≥50% in patients assessed with duplex ultrasound after one month and after one year.
- Improvement in clinical symptoms, assessed with the Rutherford classification at one month and one year. Particularly changes from Rutherford categories 2 and 3 to other categories.
- Ankle-brachial index (ABI) after one month and after one year.
- Amputation rate during follow-up, analysed when all patients have been followed for at least one year.
- Health-economic assessment after one year and during long-term follow-up (only certain centres).
Patient numbers

Critical Ischemia
- 2400

Intermittent Claudication
- 1330
Randomised patients in SWEDEPAD 16-01-24

Total 394

- SWEDEPAD 1: 254
- SWEDEPAD 2: 140

- Södersjukhuset: 101
- Karolinska universitets sjukhuset: 77
- Sahlgrenska sjukhuset: 71
- Kärllk. Jönköpings län: 48
- Halmstads Länssjukhus: 27
- Karlstad: 14
- Umeå - regionssjukhuset: 13
- Kärnsjukhuset Sköve: 12
- Helsingborgs lasarett: 12
- NÄL: 6
- Västerås - centrallasarettet: 6
- Örebro Universitetssjukhuset: 3
- Gävle - länssjukhuset: 2
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- Akademiska sjukhuset Uppsala: 1
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