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VEITH SYMPOSIUM

Will the BEST Trial Answer the Question on Iliac Stenting?

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BEST

Best Endovenous treatment, including STenting, versus best non-endovenous treatment in chronic proximal deep venous disease

Matthew Machin, Sasha Smith, David Epstein, Emma Wilton, Sandip Nandhra, Christopher Hammond, Chung Lim, Gerard O'Sullivan, Manjit Gohel, John Norrie, Beverley Hunt, Stephen Black, Joseph Shalhoub, Alun Huw Davies

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BEST

328 participants
10 centres

Inclusion criteria:

- Adult patients with chronic venous disease secondary to chronic proximal thrombotic or non-thrombotic stenosis or occlusion
- CEAP clinical C3, C4, C5, C6 or symptoms of venous claudication

Study arms

Intervention arm: best endovenous reconstruction using dedicated venous stents under guidance of IVUS

Control arm: best medical treatment alone

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328 participants
10 centres

PRIMARY OUTCOME: VCSS @ 6 months)

Secondary outcomes:

Villalta score
Stent patency
Cost-effectiveness
VEINES-QoL/Sym

Generic QoL
(SF-36, EQ-5D-5L)
Venous ulceration
Venous claudication distance

Recruitment– Internal pilot

Figure 2: Recruitment target vs actual achieved recruitment

Challenges

- Delays in acquiring local R&D approval
  - Confirmation of capacity and capability **average 243 days**
  - **Site activation from this point <14 days**
- Significant imaging requirements, lack of radiology capacity
- Participant preference i.e., unwillingness to randomise (~40% of screening failures)
- Physician lack of equipoise
- Lower than anticipated participant throughput

Going forward…

- Revised sample size
  - SD reduced from 8 units to 4 units, 328 → 106
- PTS only, no NIVLs
- Leaner trial design, less burden to sites (no scans in control arm)
- Haematology Patient Identification Centres to increase participant referrals
- Qualitative sub-study exploring the patient journey and facing randomisation, aiming to improve the quality of recruitment

Sample size re-calculation

- Planned (protocolised) revision at end of internal pilot

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Assume a slightly higher SD, of 5 rather than 4

4 units minimal change VCSS

90% power

= 106 total

- Demonstrated SD of 4 units VCSS at 12 months

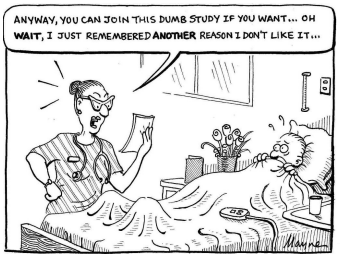
Will BEST answer the question?

- No – not by itself
- Yes – it will play a role in combination with with other trials e.g. (C-TRACT)

C-TRACT
CHRONIC VENOUS THROMBOSIS

- Nested qualitative sub-study on patient perceptions and preferences

Why do deep venous trials fail to recruit?



- STEVECO trial
- BEST trial
- (C-TRACT)

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Thank you