OXFORD POPULATION HEALTH

UNIVERSITY OF OXFORD

Registry based trials: the ultimate platform for representative enrolment

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ESC Cardiovascular Round Table: The future of clinical trials: Towards Diversity and Inclusion

Steps to inclusion

Society

Facilitate research		*Public understanding of research* *Support for research among healthcare professionals*		
Be eligible → Be invited → Be interested → Be willing → Be committed				
Protocol	*Invitation method* *Site location* *Staff burden*	*Participant materials*	*Participant materials* *Staff interactions*	*Staff interactions* *Participant engagement*

Trial team

Definitions

Registry: An organised system that collects uniform data (clinical and other) to identify specified outcomes for a population defined by a particular disease, condition or exposure

Registry-based trial: Participants are recruited and followed up within an existing registry

Example: VALIDATE-SWEDEHEART

Bivalirudin versus Heparin Monotherapy in Myocardial Infarction

Eligibility: Admitted with STEMI or NSTEMI and urgent PCI planned

Intervention: Open-label

1:1 randomisation

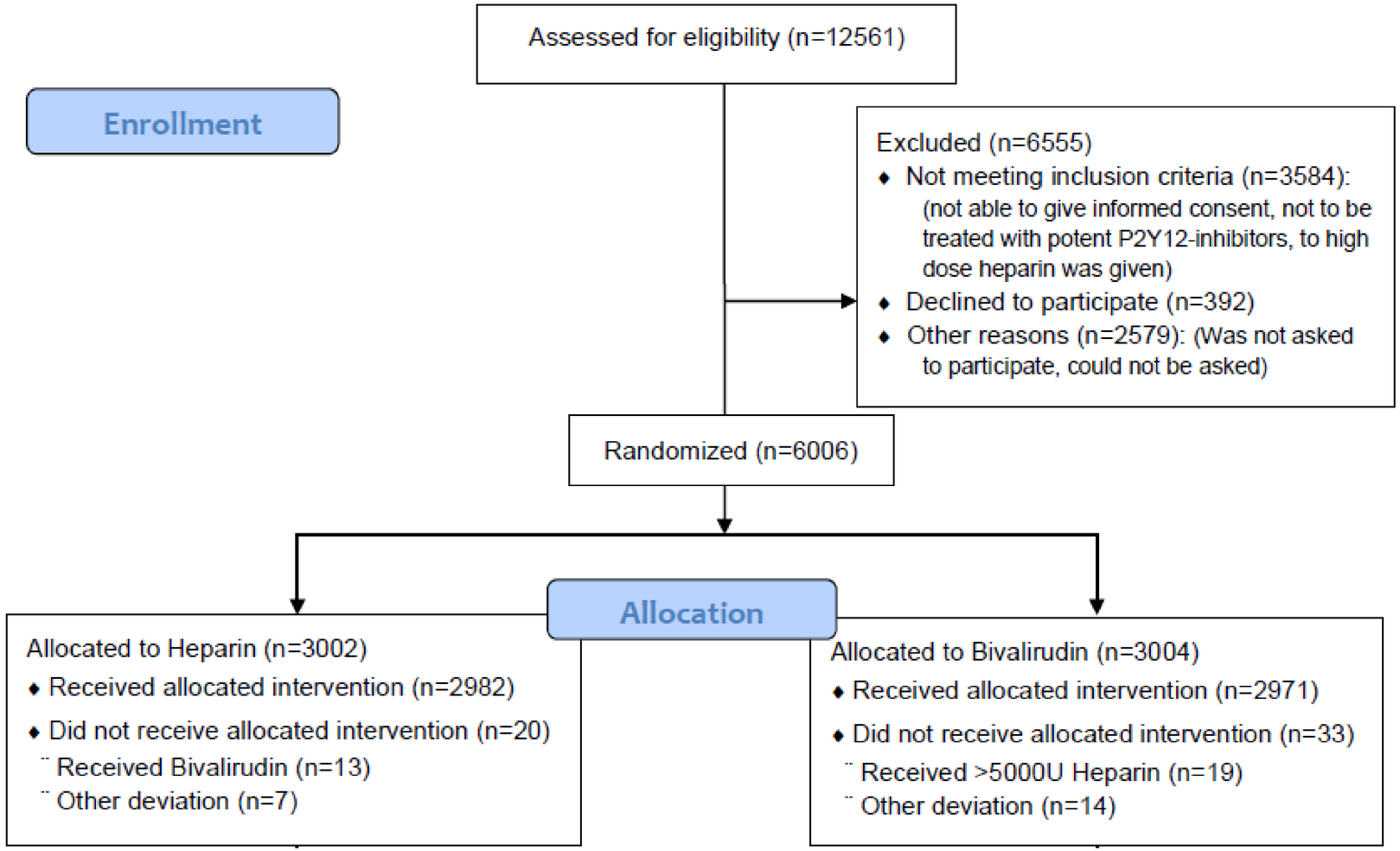
Intravenous bivalirudin vs intra-arterial unfractionated heparin

Outcome: Death, myocardial infarction, or major bleeding at 180 days

VALIDATE-SWEDEHEART: How were participants recruited?

→**Be eligible**	Simple, broad eligibility criteria
→**Be invited**	22 sites across Denmark. All relevant patients assessed
→**Be interested**	Low burden for participants
→**Be willing**	Verbal consent for STEMI participants
→**Be committed**	Telephone follow-up at 7 and 180 days

VALIDATE-SWEDEHEART: Participant enrolment



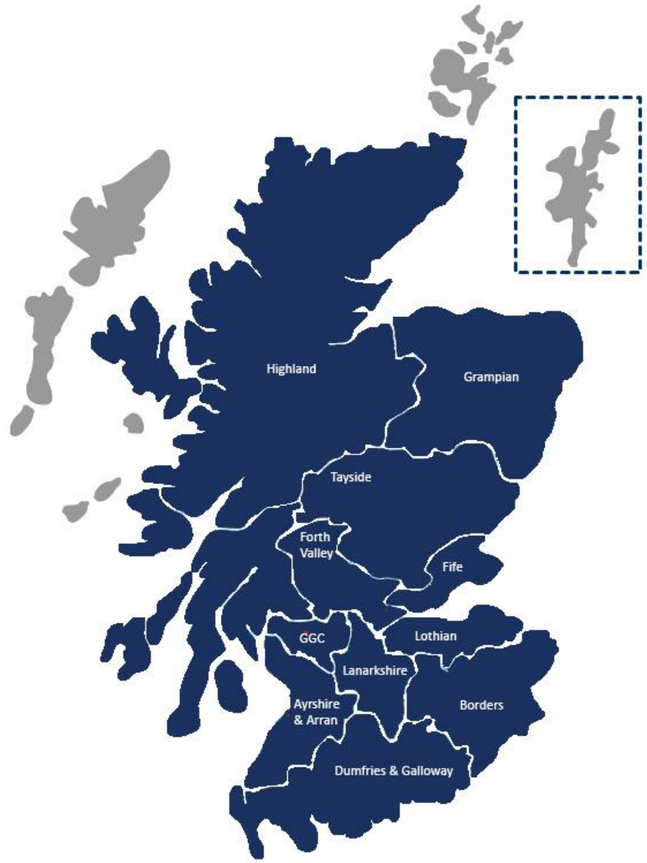
VALIDATE-SWEDEHEART: Selected baseline characteristics

Characteristic	All Patients Enrolled in the Trial (N=6006)	Screened Patients Not Enrolled in the Trial (N=6555)
STEMI — no. (%)	3005 (50.0)	2318 (35.4)
Male sex — no. (%)	4406 (73.4)	4555 (69.5)
Median age— yr	68.0	71.0
Current smoker — no. (%)	1426 (23.7)	1361 (20.8)
Diabetes — no. (%)	999 (16.6)	1631 (24.9)
Hypertension — no. (%)	3105 (51.7)	4080 (62.2)
Previous MI — no. (%)	974 (16.2)	1831 (27.9)

STEMI = ST Elevation Myocardial Infarction

LENS: fenofibrate for diabetic retinopathy

- **Trial design:** Randomised double-blind placebo-controlled trial
- **Run-in:** active, 2-3 months
- **Treatment:** 145mg fenofibrate tablet or placebo
- **Eligibility:** adults, T1DM and T2DM, observable eye disease
- **Sample size:** >1000 patients
- **Primary outcome:** progression to referable eye disease or treatment
- **NHS data linkage:** recruitment and most outcomes
- **Contact:** two visits in person, then by telephone + post



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Registry trials - key elements for inclusivity

- Broad, simple eligibility (where-ever possible)
- Low burden of data collection for sites and participant
- Recruitment embedded in clinical care (acute/one-off interventions)
- Opportunities for direct-to-participant national mail-based recruitment (long-term treatments)