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Does nicorandil instead of supranormal potassium safely provide cardioplegia?

Submission date	Recruitment status	[_] Prospectively registered
25/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2021	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Does nicorandil instead of supranormal potassium safely provide cardioplegia?

Study objectives
Nicorandil instead of supranormal potassium in cardioplegia is feasible, providing cardiac arrest and protection.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Helse Nord research fund.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Angina pectoris

Interventions
Two groups of cardioplegia randomised to receive either:

1. Standard St. Thomas Hospital Solution (high [16 mM] potassium cardioplegia)
2. Nicorandil

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nicorandil

Primary outcome(s)
1. Creatine Kinase Myocardial Band (CKMB)
2. Troponin
3. Cardiac Index (CI)
4. Saphenous Vein (SV)
5. Systemic Vascular Resistance (SVR)
6. Heart rate (HR)
7. Time to arrest

Key secondary outcome(s)
Quality of life

Completion date
26/09/2005

Eligibility

Key inclusion criteria

1. Aged 40 to 75 years
2. Elective to Coronary Artery Bypass Graft (CABG)
3. Ejection Fraction (EF) more than 40%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Concomitant procedures
2. Emergency procedures
3. Glibenclamid medication
4. Pregnancy

Date of first enrolment
24/01/2005

Date of final enrolment
26/09/2005

Locations

Countries of recruitment
Norway

Study participating centre
Breivika
Tromsoe
Norway
9038

Sponsor information

Organisation

University Hospital of North Norway (Norway)

ROR
https://ror.org/030v5kp38

Funder(s)

Funder type
Government

Funder Name
Local Health Authorities

Funder Name
University Hospital of North Norway

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/07/2006	07/01/2021	Yes	No