

Does nicorandil instead of supranormal potassium safely provide cardioplegia?

Submission date 25/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/01/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

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.

Study design

Randomised controlled trial

Primary study design

Interventional

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

Tromsø

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