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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## 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 measure

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

### Secondary outcome measures
Quality of life

### Overall study start date
24/01/2005

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
50

### 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)

### Sponsor details
Breivika
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### Sponsor type
University/education

### Website
http://www.unn.no/

### 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

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## 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 |