ISRCTN67437862 https://doi.org/10.1186/ISRCTN67437862

A randomised, double-blind, placebo-controlled study of Glypromate® in patients undergoing coronary artery bypass graft surgery

Submission date 19/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/01/2006	**Overall study status** Completed	
Last Edited 21/09/2007	**Condition category** Surgery	

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
Neu-GPE-CABG-001

Study information

Scientific Title

Acronym
SNUG (Studying Neurons Using Glypromate®)

Study objectives
Study is designed:
1. To determine the pharmacokinetics of Glypromate® in patients undergoing Coronary Artery Bypass Graft (CABG) surgery with/without valve replacement/repair
2. To show that Glypromate® use is not associated with major adverse events when compared to placebo in people undergoing CABG surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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
Coronary Artery Bypass Graft (CABG) surgery

Interventions
This phase two study will be conducted in two stages:

In stage 1 (conducted at the Principal Investigator's site only), patients will be randomised in a 1:1 fashion to receive intravenous (IV) Glypromate® 1 mg/kg/hr for four hours or 3 mg/kg/hr for four hours. Two to four patients are expected to be enrolled into this open-label stage of the study.

In stage 2, participants from five centres will be randomised in a 1:1:1 fashion to receive IV Glypromate® 1 mg/kg/hr for four hours or IV Glypromate® 3 mg/kg/hr over four hours or IV Placebo (normal saline) for four hours. The Glypromate®/Placebo infusion will commence at the start of chest closure.

Participants will be observed from randomisation through to discharge or day 14, whichever comes sooner.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Glypromate®

Primary outcome measure
To determine the pharmacokinetics of Glypromate® in patients undergoing CABG surgery to assess dose-response relationships.

Secondary outcome measures
To monitor the safety profile of Glypromate® treatment compared to placebo in patients undergoing CABG. Data will be collected through to discharge or day 14 whichever comes first.

Overall study start date
26/09/2005

Completion date
28/02/2006

Eligibility

Key inclusion criteria
Participants must meet all of the following criteria:
1. Be at least 60 years of age
2. Be scheduled for non-urgent, on-pump CABG surgery
3. Be willing to provide written informed consent
4. Be agreeable to be undergo all study tests (collection of blood for PK assessment)

The Glypromate®/placebo infusion will be commenced at the start of chest closure providing the following criteria are met:
1. The patient has been successfully weaned off the bypass pump
2. The patient does not have an Intra-Aortic Balloon Pump (IABP)
3. The anaesthetist has assessed the patient as having no contraindications to receiving Glypromate®/placebo medication

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
30

Key exclusion criteria
A participant will be ineligible if he/she meets any of the following criteria:
1. Body weight less than 55 kg or more than 120 kg
2. Scheduled to undergo a significant concomitant surgical procedure (e.g. carotid endarterectomy, aortic root repair or replacement, Deep Hypothermic Circulatory Arrest [DHCA] or pulmonary resection)
3. Has a pre or perioperative mechanical assist device or IABP inserted for shock/low output syndrome
4. Renal insufficiency (serum creatinine greater than 0.17 mmol/l) or renal failure requiring dialysis
5. Chronic hepatic failure and/or cirrhosis
6. History of significant haematologic or coagulation disorders, including thrombocytopenia (platelet count less than 50,000), known hypercoagulable state, or recurrent deep vein thrombosis
7. Current participation or participation within the seven days prior to the start of this study in another investigational drug or device study
8. History of or any current condition that in the investigator's opinion would interfere with study participation or evaluation of results

Date of first enrolment
26/09/2005

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
New Zealand

Study participating centre
University of Auckland
Auckland
New Zealand
1031

Sponsor information

Organisation
Neuren Pharmaceuticals Limited (New Zealand)

Sponsor details
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Sponsor type
Industry

Website
http://www.neurenpharma.com

ROR
https://ror.org/0503fq502

Funder(s)

Funder type
Industry

Funder Name
Grant from a New Zealand Government Agency, Foundation for Research Science and Technology.

Funder Name
Grant type: Technology for Business Growth

Funder Name
Grant title: Implementation for Phase II for Glypromate

Funder Name
Study is also internally funded by Neuren Pharmaceuticals Limited (New Zealand)

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