



How to Randomise and Commence the NeogluCO Study (ACH)

NO EXCLUSIONS

- Confirmed major congenital malformation or chromosomal disorder
- Suspected genetic syndrome associated with hypoglycaemia, e.g., Beckwith Wiedemann Syndrome
- Gastrointestinal disorder likely to affect feed tolerance
- Planned or likely neonatal surgery
- Confirmed sepsis (culture of pathogenic organism from blood, CSF or urine)
- Hypoxic ischaemic encephalopathy
- Family history of congenital hyperinsulinism
- Suspected inborn error of metabolism
- Triplets

MEETS ALL INCLUSION CRITERIA

- ≥ 35 GA AND < 8 days old (< 169 hours)
- Admitted to NICU with recurrent/severe hypoglycaemia defined as one or more of the following:
 - ≥ 3 episodes of hypoglycaemia < 2.6 mmol/L in 48 hours
 - Blood glucose of 1.2 to < 2.0 mmol/L persisting after 2 doses of dextrose gel & feeding in a single episode
 - Any episode of hypoglycaemia < 1.2 mmol/L.
- Babies must be receiving ongoing management for hypoglycaemia at the time of randomisation e.g., IV dextrose, carbohydrate supplements, continuous or frequent feeding (≤ 2 hourly), or inability to wean off formula due to hypoglycaemia
- Twins may be included



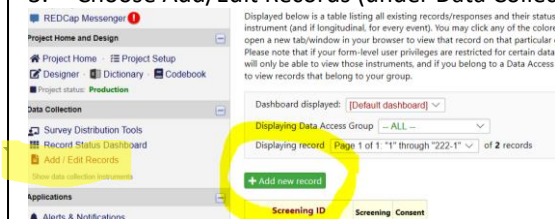
INFORMED WRITTEN CONSENT

1. Collect study pack from NeoGluCO trolley
2. Complete hard copy consent and keep original at bedside; give parents a copy
3. Sign NeoGluCO consent label and place in medical notes

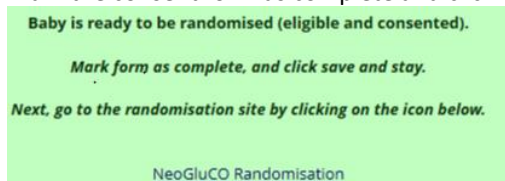


COMPLETE SCREENING

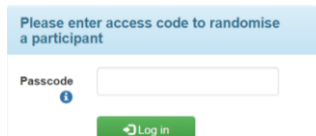
1. Access the screening database from the research page: Paanui/Kidzfirst/Neonatal Clinical Guidelines/Research Studies/NeoGluCO/SCREENING <https://redcap.liggins.auckland.ac.nz/redcap_v9.1.2/index.php?pid=70>
2. Login:
 - Username: Middlemore_30
 - Password: 319584Mid
3. Choose Add/Edit Records (under Data Collection on LH side)



4. Click the green button 'Add new record' and fill out the screening form.
 - Maternal: NHI, DOB, EDD, Plurality, relevant family history
 - Baby: NHI, DOB & time, birth order, BW & customised centile, sex, BG history
5. Mark the screening form as complete and click 'Save and go to next form'
6. Fill out the consent form.
7. Mark the consent form as complete and click 'Save and stay' then click on 'NeoGluCO Randomisation' in the green box



8. Use the screening password to access the randomisation system: 319584Mid



Contact the research team at any stage to assist with screening and consent.

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RANDOMISE

1. **Eligibility Form:** enter the baby's NHI and click "**Check in Screening DB**". This will import data from the screening database. If the imported details are correct, click next for Enrolment.

Check for eligibility

C. Check Eligibility (NEO GluCO screening criteria)

Please enter participant's NHI to check eligibility in the screening database.

Participant NHI (NHI):

View/Hide screening

X. Entry Criteria

All must be yes

X.1. $T \le 25$ weeks' gestation

X.2. Currently admitted to neonatal unit (0.3 to 1.2)

X.3. $A \le 48$ days old (168 hours)

X.4. No existing ongoing complications for hyperglycaemia, e.g. IV diabetes, continuous or frequent feeding or P_{20} carbohydrate supplements

Any must be yes

X.5. $T \le 3$ episodes of hyperglycaemia > 6.0 mmol/L in 48 hours

X.6. Blood glucose of 1.2 to > 2.0 mmol/L, persisting after 2 doses of dextrose gel and feeding

X.7. $T \le 1$ episode of hyperglycaemia > 3.0 mmol/L

Y. Exclusion Criteria (all must be no)

Y.1. Confirmed major congenital malformation or chromosomal disorder

Y.2. Suspected inborn error of metabolism

Y.3. Suspected congenital hypercalcaemia or other endocrine disorder affecting glucose and insulin metabolism

Y.4. Gastrointestinal disorder likely to affect feed tolerance

Y.5. Jaundice

Y.6. Planned or likely neonatal surgery

Y.7. Confirmed sepsis by blood, urine, CSF culture

Y.8. Hypoxic ischaemic encephalopathy

Y.9. Family history of congenital hypercalcaemia

2. **Enrolment Form:** check data are correct and click 'yes' on the last question 'R11 Participant detail verified', then click **SUBMIT**

NeoGluCO Randomisation Home

ELIGIBILITY ENROLMENT TREATMENT SUMMARY STOCK DATA MANAGEMENT LOG OUT

Randomisation

R1.1 Site:

R1.2 Baby NHI: Participant has consented and available to participate in the study.

R1.3 Consented:

R1.4 Date of birth:

R1.5 Sex:

R1.6 Small for gestational age:

R1.7 Name:

R1.8 Maternal NHI:

R1.9 Priority Number of Intakes:

R1.10 Birth order:

R1.11 Participant detail verified:

- This will generate the Study ID and randomisation sheet which can be printed.
- Go to '**Treatment**' tab and click '**allocate**' to get the study drug bottle number (NGxxxx)
- The randomisation sheet can also be accessed by going to '**Summary**' tab and entering the baby's NHI

PRESCRIBE INTERVENTION

Consultant/Fellow/NP to prescribe randomised intervention on medication chart (see example below)

- Prescribe NeoGluCO Study Drug **loading dose** on stat chart at 0.5 ml/kg PO/NGT
- Prescribe NeoGluCO Study Drug **maintenance dose** on regular chart at 0.15 ml/kg every 12 hours PO/NGT (commencing 12 hours after loading dose)

BASELINE PROCEDURES

- Check baseline bloods have been collected.
 - Blood gas within last 6 hours
 - Plasma insulin/betahydroxybutyrate/free fatty acids/creatinine/glucose. If not already taken on admission, collect hypo/baseline pack from NeoGluCO trolley and collect blood.
- Study team member will insert and set up continuous glucose monitor as soon as able

START INTERVENTION

- Take randomisation summary to medication room and find bottle that matches the study bottle allocation number
- Place patient label on bottle (bottles not to be shared between babies)
- Shake and administer loading dose as per med chart (PO or NGT); can be given by syringe, with feed, or via NGT with 0.5 ml normal saline flush
- Sign for administration on med chart and store in bedside fridge

CONTINUE INTERVENTION

- Give two maintenance doses 12 hours apart at 0.15ml/kg as charted
- Once two maintenance doses have been given:
 - Collect Blood Samples B (see trolley for blood collection pack)
 - Titrate doses every 12 hours as per titration protocol



Once Only

Date	Medicine	Units	Route	Dose calculation (to right per dose)	Prescriber	Time commenced
15/5/20	NEOGLUCO STUDY DRUG	0.5	PO	0.5 ml/kg	Chris McKinlay FRACP NZMC 23135	1730
	Loading dose				Pharmacy & special instructions	Time completed
					Flush with water	1780

Regular Medicine

Date	Medicine	Units	Route	Frequency	Dose calculation (to right per dose)	Prescriber	Time completed
15/5/20	NEOGLUCO STUDY DRUG	0.15	PO	12h	0.15 ml/kg	Chris McKinlay FRACP NZMC 23135	
						Sign, date and time to cancel	
					See titration protocol		