NEO GLU C O
Neonatal Glucose Care Optimisation Study

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

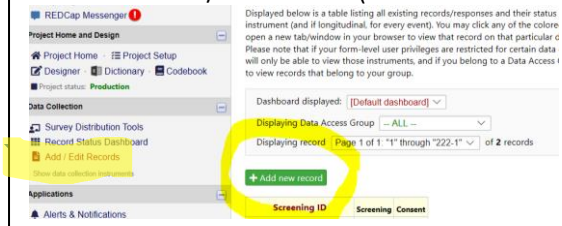
- ≥ 35 GA AND < 8 days old (<169 hours)
- Admitted to NICU with recurrent/severe hypoglycaemia defined as one or more of the following:
    - ≥3 episodes of hypoglycaemia <2.6 mmol/L in 48 hours
    - Blood glucose of 1.2 to <2.0 mmol/L persisting after 2 doses of dextrose gel & feeding in a single episode
    - 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

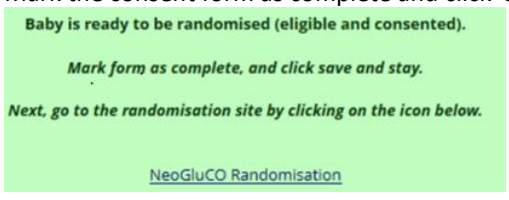
1. Collect study pack from NeoGluCO trolley
2. Complete hard copy consent and keep original at bedside; give parents a copy
3. Sign NeoGluCO consent label and place in medical notes

COMPLETE SCREENING

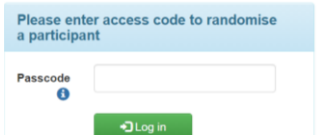
1. Access the screening database from the research page: Paanui/Kidzfirst/Neonatal Clinical Guidelines/Research Studies/NeoGluCO/SCREENING <https://redcap.liggins.auckland.ac.nz/redcap_v9.1.2/index.php?pid=70>
2. Login:
    - Username: Middlemore_30
    - Password: 319584Mid
3. Choose Add/Edit Records (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.
Study phone 021897982; Chris McKinlay 0274725099

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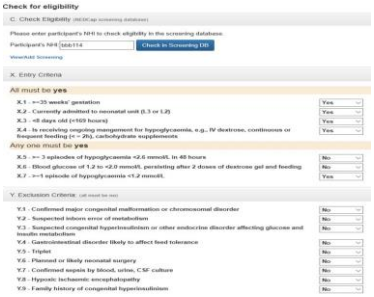
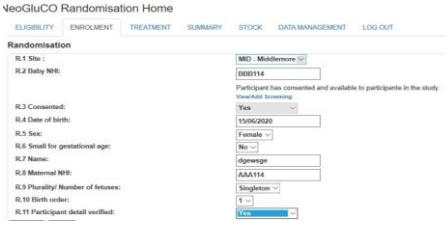
RANDOMISE

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.



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



3. This will generate the Study ID and randomisation sheet which can be printed.
4. Go to **'Treatment'** tab and click '**allocate**' to get the study drug bottle number (NGxxxx)
5. 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)

1. Prescribe NeoGluCO Study Drug **loading dose** on stat chart at 0.5 ml/kg PO/NGT
2. 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

1. 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.
2. Study team member will insert and set up continuous glucose monitor as soon as able

START INTERVENTION

1. Take randomisation summary to medication room and find bottle that matches the study bottle allocation number
2. Place patient label on bottle (bottles not to be shared between babies)
3. 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
4. Sign for administration on med chart and store in bedside fridge

CONTINUE INTERVENTION

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