# Neonatal Unit Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Contacts</th>
<th>G A / B W C r i t e r i a</th>
<th>Eligibility</th>
<th>Consent</th>
<th>Links</th>
</tr>
</thead>
</table>
| PLUSs | Daytime: Lisa Mavricich 021897982 or Chris McKinlay 0274725099  
After hours: Chris McKinlay 0274725099  
<28 weeks |  
No weight restriction | Inclusion:  
- <48 hours  
- Surfactant if given, <12 hours ago  
- Receiving mechanical ventilation via an endotracheal tube or receiving non-invasive respiratory support including CPAP, nasal IPPV or nasal high flow AND a clinical decision to treat with exogenous surfactant  
Exclusion:  
- Previous steroids for prevention of lung disease  
- Infant considered non-viable/not going to be admitted to NNU or likely to transfer to nonparticipating NNU within 24 hours of birth  
- Major congenital anomaly | Written informed consent prior to randomisation.  
NEW! babies can be recruited to both PLUSs and ABC. | Randomisation  
Databases  
Flow Chart  
Quick Guide  
Consent and Forms  
Health Professional Brochure  
Protocol  
Study Handbook |
| ABC | Daytime: Elizabeth Nevill 021300877  
After hours: duty consultant  
<31 weeks |  
En caul delivery  
Short umbilical cord | Exclusion:  
- Twin to twin transfusion  
- Placental abruption  
- Congenital abnormality  
- Severe antenatal IUGR | If unable to obtain consent antenatally, randomise based on a waiver of consent with informed, written consent obtained within 24 hours. | Consent Form  
Deferred Consent Form Antenatal Protocol |
### DIAMOND

**Daytime:** Tanith Alexander  
**After hours:** Tanith until 8 pm  

<table>
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<tr>
<th>32+0 to 35+6 weeks</th>
<th>Inclusion:</th>
<th>Exclusion:</th>
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</table>
| >24 hours of age | - Mother intends to breastfeed  
- Insertion of intravenous lines based on clinical need  
- Domicile in Auckland | - A particular mode of nutrition is clinically indicated  
- Congenital abnormality likely to affect growth, body composition or neurodevelopmental outcome |

Written informed consent prior to randomisation.

### PAEAN

**Daytime:** David Hou or Lisa Mravicich  
**After hours:** duty consultant  

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<tr>
<th>&gt;=35 weeks</th>
<th>Inclusion:</th>
<th>Exclusion:</th>
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| <23 hours | - One or more of the following: Apgar 5 at 10 mins after birth; OR receiving ongoing resuscitation at 10 mins after birth; OR on cord blood or arterial/venous blood obtained at < 60 mins after birth, pH less than 7.00 OR base deficit 12.0 mmol/L.  
- Moderate to severe encephalopathy, defined between one and six hrs after birth by: 3 out of 6 modified Sarnat criteria indicating moderate/severe encephalopathy  
- Hypothermia treatment initiated by 6 hrs of age; Study treatment planned to start within 24 hrs after birth  
- At least one parent 18 yrs old  
- Anticipated ability to collect primary endpoint at 2 yrs | - Severe IUGR (birth weight <1800 g)  
- Suspected major chromosomal or congenital anomalies  
- HC <3rd centile below mean for GA & gender  
- Imminent withdrawal of care is being planned |

Written informed consent prior to randomisation. Where this cannot be obtained in time to allow randomisation by 23 hours of age, telephone parental consent is acceptable, with signed consent obtained as soon as feasible.
<table>
<thead>
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<th>Inclusion:</th>
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<tbody>
<tr>
<td>- &lt;8 weeks old</td>
<td>- Previous exposure to paracetamol or ibuprofen</td>
</tr>
<tr>
<td>- Chronic disease associated with limited life expectancy (&lt;6 years)</td>
<td>- Likely to leave NZ in first 6 years</td>
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Written informed consent prior to randomisation.

<table>
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<tr>
<th>Randomisation</th>
<th>Data bases</th>
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<tbody>
<tr>
<td>Consent Forms</td>
<td>Readmission to Kidz First Protocol Health Professional Brochure Parent Brochure (Postnatal) Health Protocol Standard Operating Procedures Sitedocs Portal Test Data base</td>
</tr>
</tbody>
</table>
Daytime: Lisa Mravicich 021897982
or Chris McKinlay 0274725099

After hours: Chris McKinlay 0274725099

34+0 to 36+6 we eks

Inclusion:
- <72 hours

Exclusion:
- Major congenital abnormality
- Minor congenital abnormality likely to affect respiration, growth or development
- Previous caffeine treatment
- Renal or hepatic impairment
- Tachyarrhythmia
- Seizures
- Hypoxic ischaemic encephalopathy
- Residing outside of the Auckland DHB regions

Written informed consent prior to randomisation.

Publications

2019


2018

2018


2014


2013

• Meyer M, Manzoni P. Lactobacillus GG as probiotic for prevention of necrotizing enterocolitis or late onset sepsis in preterm infants: an updated meta-analysis. Early Hum Dev. 2013;89s1:S84.

2012