

Welcome to Newsletter 36 for the C*STEROID Trial

Can we safely reduce the risk of breathing problems for newborn babies by giving corticosteroid injections to their mothers before a planned caesarean section?

RECRUITMENT UPDATE

KEEP WARM &



Winter has officially arrived in the Southern Hemisphere. We hope everyone is keeping warm and healthy during this chilly season. In May, we welcomed a total of 43 babies to the C*STEROID trial, bringing our overall total to 1,398 babies.

A big shout out to **Monash Health**, who topped the recruitment leaderboard this month with an impressive nine recruits! Fabulous job, team!

KEEP RECRUITING



Also, congratulations to **Mater Mothers' Hospital** on their first recruit, and a warm welcome to **Frances Perry House** for joining the C*STEROID team.

Well done to the **five sites who successfully met their targets in May** – Awesome work!

Let's keep this fantastic momentum going and make this winter a season of even greater achievements!



CLINICIAN OF THE MONTH

Congratulations to Ayumi Salim at St George Hospital for being our C*STAR of the month!

Ayumi is a midwife working in antenatal clinic at St George Hospital in Sydney, Australia.

Here is what she shared about her experience with the C*STEROID trial:

"I really like engaging in conversation with women eligible to be recruited into the trial and promoting it amongst the antenatal clinic."



Ayumi Salim

GUIDE TO PROTOCOL DEVIATIONS & WITHDRAWALS

PART ONE

Do you know when to report protocol deviations and withdrawals?

We have created a dedicated column in this month's and next month's newsletter to provide tips on reporting and managing protocol deviations and withdrawals.

Protocol Deviations (Complete CRF 11)

Type of Protocol Deviation	Example
Randomised in error	<ul style="list-style-type: none">Randomised not eligible participantRandomised before receiving written consent, then later changed their mind about participation
Intervention discontinued (first/second dose not given despite participant remaining pregnant).	<ul style="list-style-type: none">Participant withdrawal after randomisationBirth plan changed to normal vaginal birth before study drug administrationParticipant didn't attend first or second visitSevere reaction to first dose, second dose not given
Major non-compliance with intervention	<ul style="list-style-type: none">Study drug/s given outside the allowed window (two doses given but <20 hours or >28 hours apart)Incorrect route of administration
No neonatal blood sugar measurements	<ul style="list-style-type: none">Ward staff unaware, and the baby did not receive glucose testing in the first 12 hours of life
Incorrect intervention	<ul style="list-style-type: none">The study drug kit number administered was different to the kit number allocated by the randomisation system
Randomised in wrong stratum	<ul style="list-style-type: none">Incorrect entry of EDD/GA/pregnancy type (singleton/twin) during randomisationIncorrect calculation of GA due to coding error - feasibility study
Other	<ul style="list-style-type: none">Written consent obtained after randomisation

Withdrawal of Consent (Complete CRF 12)

The Participant Withdrawal Form is to be completed **only when the participant explicitly requests withdrawal** or at the discretion of the investigator.

- Full withdrawal** – if no further study participation, data collection or follow-up contact
- Reduced participation** – declined some outcome assessments but continued collection of data +/- no further follow-up contact (If 6-week postnatal questionnaires are not yet sent, select 'No' in CRF5 Maternal Outcome)

PHOTOS FROM THE MAY EVENT - CELEBRATE INTERNATIONAL CLINICAL TRIALS DAY WITH C*STEROID & PRECeDe

Huge thanks from us to all who celebrated International Clinical Trials Day with innovative events to actively promote the C*STEROID and PRECeDe trials to engage clinicians and potential participants. From hosting booths at GP conferences and local hospitals to dedicating mornings in clinic rooms, our remarkable team of trial advocates have been working tirelessly all through May.

This event provided a great opportunity to **update the clinicians on the latest ACS (antenatal corticosteroids) evidence**. If you haven't seen the educational video yet, please [click here](#) to watch it and share it with your colleagues or use it in local education sessions. We encourage you to **continue utilising this resource**.

[Click here](#) or scan QR code to watch the video on latest ACS evidence



Below are snapshots of our wonderful teams across Australia and New Zealand.

Thank you once again for sharing these photos!❤️



Ranking	Start date	Site	Monthly Target	Total (babies)	Last month
1	Jun 2023	Monash Health (VIC)	5	53	9
2	Oct 2023	Waitematā (Auckland)	2	24	7
3	Oct 2020	National Women's Health, Auckland	14	481	6
4	Feb 2021	Christchurch	10	225	6
5	Jan 2025	Barwon Health (VIC)	4	16	6
6	Feb 2023	Sunshine/Bacchus Marsh (VIC)	9	108	3
7	Jun 2023	Ballarat Base Hospital Grampians Health (VIC)	3	21	2
8	Apr 2023	Royal Women's Melbourne (VIC)	5	40	1
9	Jun 2022	Middlemore (Auckland)	3	35	1
10	Jun 2023	Northern Hospital (VIC)	1	3	1
11	Mar 2025	Mater Mothers' Hospital (QLD)	1	1	1
12	Nov 2020	Waikato	4	144	0
13	Oct 2021	Wellington	3	52	0
14	Apr 2023	Royal Hospital for Women (NSW)	4	34	0
15	Apr 2023	Mercy Hospital for Women (VIC)	4	34	0
16	Mar 2021	Tauranga	-	28	0



17	Apr 2023	St George (NSW)	2	24	0
18	Jul 2023	Ipswich Hospital (QLD)	3	19	0
19	Jun 2023	Women's and Children's Hospital Adelaide (SA)	3	18	0
20	Jun 2024	Campbelltown Hospital (NSW)	2	14	0
21	Jun 2023	Royal Brisbane and Women's (QLD)	3	12	0
22	Apr 2021	Northland	-	5	0
23	Mar 2024	John Hunter Hospital (NSW)	1	2	0
24	Apr 2024	Fiona Stanley Hospital (WA)	1	1	0
25	May 2025	Frances Perry House (VIC)	1	0	0
26	Jun 2023	Townsville Hospital (QLD)	-	1	0
27	Jun 2023	Liverpool Hospital (NSW)	-	0	0
28	Jun 2023	Eastern Health Box Hill (VIC)	-	0	0
*	Apr 2023	Royal North Shore (NSW)	-	3	-


= New sites

= Moved up leaderboard

= Met monthly site target

1398

43



New site - Frances Perry House

Frances Perry House is a private maternity hospital in Melbourne. We extend a warm welcome to the team. We're thrilled to have you on board!

Huge high-fives to **Monash Health** for claiming the top spot on the leaderboard this month. Congratulations, team!

Superb work **Waitemata** for exceeding your monthly target again this month with dazzling 7 recruits!

- Other sites to celebrate this month:
- Barwon Health
 - Sunshine
 - Grampians Health
 - Middlemore
 - Mater Mothers' Hospital