

Guidance Sheet 11: Withdrawal & Unblinding

Withdrawal

- Staff can withdraw a baby from the AZTEC trial or discontinue AZTEC IMP at any time if parents wish or if it is deemed necessary for baby treatment.
- Parents do not have to give a reason for withdrawing a baby. Please ensure that you ask if:
 - The parents agree that the data already collected can be used
 - The parents agree that clinical data can be collected until their baby is discharged/reaches the end of the trial participation period
 - The parents agree for sample collection to continue
 - The parents agree to be contacted for later follow-up (if they originally consented)
- The time and date at which the baby was withdrawn from the clinical trial or the intervention discontinued should be documented in the baby's medical notes, together with any other necessary information.

Emergency Unblinding

- Emergency unblinding should only be carried out if the clinician carrying out the unblinding procedure is certain that:
 - A) This is a **genuine emergency** AND
 - B) Knowledge of the treatment allocation (either azithromycin or placebo) is **necessary to guide the clinical management of the participant.**
- Appropriate clinical management will be possible in the majority of cases without the need for unblinding by treating the participant as though they have received azithromycin.

Web-based procedure for emergency unblinding:

- Emergency unblinding must be conducted by a medically qualified individual who is named on the delegation log
- During office hours (Monday-Friday 09:00-17:00), an attempt should be made to contact the Chief Investigator or designated clinical reviewer via the CTR (Tel: 029 2068 7990) to discuss the circumstances under which unblinding is being considered

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- An **Unblinding CRF** (in document box) should be completed prior to conducting unblinding, where possible
- In the AZTEC document box there is a sealed envelope containing the following information:
 - AZTEC randomisation website address
 - Single-use login details and password

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- Once logged in, select the “Blind” menu in the top right-hand corner to highlight Unblind, and then “By site participant”

Azithromycin Therapy for Chronic Lung Disease of Prematurity (AZTEC)
The trial is a two-arm placebo-controlled trial investigating the effect of IV azithromycin on survival without chronic lung disease in preterm neonates

Demo

Participants

IV azithromycin on survival without chronic lung disease in preterm neonates >>> Centre 11

AZTEC
Azithromycin Therapy for Chronic Lung Disease

Blind Help Logout
Unblind *
By Site Participant

Randomised Participants

Subject ID	Allocation	Randomised By	On	At
1101	1754	mpoddard	Tue 04 Jun 2019	12:03
1102	1772	mpoddard	Tue 04 Jun 2019	12:53
1103	1977	mpoddard	Tue 04 Jun 2019	12:55
1104	1716	mpoddard	Tue 04 Jun 2019	13:04
1105	1953	mpoddard	Tue 04 Jun 2019	15:31
1106	1082	randomizer11	Mon 17 Jun 2019	10:20
1107	1034	slowe	Mon 17 Jun 2019	13:50

1 to 7 of 7 entries
Save to File (.csv)

Unblind11

Primary Care Clinical Trials Unit

The Nuffield Department of Primary Care Health Sciences
Raddiffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG
Tel: +44 (0)1865 289 300

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- Carefully select the appropriate **Study ID**, and select unblind

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Demo

Participants Unblind Site Participant

IV azithromycin on survival without chronic lung disease in preterm neonates >>> Blind >>> Unblind Site Participant

AZTEC
Azithromycin Therapy for Chronic Lung Disease

Blind Help Logout

Unblind by Site Participant

Select Participant 1101

Unblind

Unblind11

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- The system will then reveal the arm allocation of the infant- **knowledge of the allocation** should be strictly limited to those individuals who need to know for guiding the clinical management of the baby

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Demo

AZTEC
Azithromycin Therapy for Chronic Lung Disease

Participants Unblinding Blind Help Logout

IV azithromycin on survival without chronic lung disease in preterm neonates >> Blind >> Unblind Study

Unblinding						
Subject ID	Site	Group	Allocation	Randomised On	At	By
1101	Centre 1	Placebo	54	Tue 04 Jun 2019	12:03	randemo_mgoddard

[Save to File \(.csv\)](#)

Unblind11

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- After the unblinding procedure is completed, please email or fax the **Unblinding CRF** to the CTR as instructed on the form
- The AZTEC Trial Team will be automatically informed of any cases of unblinding.

Back-up procedure for emergency unblinding:

- In the event the randomisation website cannot be accessed (e.g. issues with login details or access to the website), CTR can be contacted during office hours (Monday-Friday 09:00-17:00) to perform unblinding on behalf of a site
- Contact the pharmacovigilance and safety team on 029 2068 7462, CTR-Safety@Cardiff.ac.uk with the particulars of the request, **including the baby's Study ID**. Please note that the team may wish to facilitate a discussion with the Chief Investigator or designated clinical reviewer prior to actioning the request
- The treatment allocation of the baby will be transmitted to a named individual at site using a password protected email- **knowledge of the allocation** should be strictly limited to those individuals who need to know for guiding the clinical management of the baby