Guidance Sheet 2: Screening and consent

AZTEC Azithromycin Therapy for Chronic Lung Disease

Cardiff University Prifysgol Caerdydd

Centre for Trials Research Canolfan Ymchwil Treialon

Eligibility

Babies will be considered **eligible** for inclusion in the trial if:

a) They were born at <30 (up to 29w^{+6d}) weeks of gestation (including infants born as one of a multiple birth)

b) Have received respiratory support for at least 2 continuous hours duration during the first 72 hours of life (intubated, or by non-invasive mechanical ventilation including continuous positive airway pressure and high flow nasal cannula or a combination thereof)

c) Have an indwelling intravenous line for drug administration

d) Written informed consent has been obtained within 72 hours of birth

e) It is anticipated administration of first dose can begin within 72 hours of birth

f) It is reasonable to expect completion of 10 days of trial treatment whilst resident at the recruiting site

g) They are Inborn, or born at site within the recruiting site's neonatal network where follow up will be possible

h) In the opinion of the PI, they are likely to survive past 72 hours after birth

Babies will be **excluded** from participation in the trial if:

a) They have been exposure to another systemic macrolide antibiotic (not maternal): Including azithromycin, erythromycin, clarithromycin

b) There is presence of major surgical or congenital abnormalities (not including patent ductus arteriosus or patent foramen ovale)

c) There is a contraindication of azithromycin as specified in the summary of characteristics of the product

d) There is participation in another interventional trial that precludes participation in AZTEC

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Screening

To ensure that potentially eligible babies are not missed, it is important that all NICU staff are familiar with the AZTEC Protocol and can help with identification and recruitment.

Try to identify parents of potential recruits as early as possible in the antenatal wards, delivery suites and NICU.

- Please ensure that the Screening Log is completed and records all infants born less than 30 weeks' gestation. This should be done at least once a week using the eCRF . Please keep the log up to date by adding cases on a weekly basis. This should not include any personal identifiable information.

Informed consent

Consent may be carried out by any healthcare professional that has received **AZTEC training and GCP training** and is listed on the **Site Delegation Log** to take consent. However, please also **check** with your NHS organisation who may have more specific requirements.

1. Approach the parents to discuss the trial and provide a Parent Information Leaflet (located in the AZTEC document box). Ensure they are aware that participation is voluntary, and that consent may be withdrawn at any time without explanation.
2. Allow sufficient time for parent(s) to consider their decision and arrange a follow-up meeting to answer questions. Sometimes several meetings are needed.
3. As soon as the parent(s) decide that their baby may participate in the trial, the Consent Form must be completed. Written consent must be obtained before a baby may be randomised.
4. Written consent must be obtained before a baby may be recruited to AZTEC. Only the mother or father, or person designated formally by legal process, may sign the consent form.

- In law, unmarried fathers do not automatically have parental responsibility for their child, unless they are named on the birth certificate, or through a court order or parental responsibility agreement this can be given to them.
- In the case of twins or triplets, **each baby must** have a **separate signed consent form** and please indicate on the form the birth order of the baby (e.g. twin 1, triplet 3).

- The AZTEC trial involves recording the mother's information, so the mother must provide written consent. The father may sign the consent form (if he is married to the mother, named on the birth certificate/have been granted parental responsibility through a court order or parental responsibility agreement), but the mother must also counter-sign to provide written consent.

The consent process (i.e. important points to be covered in discussion) is discussed in more detail in **Guidance Sheet 3: Notes on informed consent**

TRANSLATORS

If a translator is used to explain the study and obtain informed consent, this must be an **adult who is unrelated to the parent** (hospital translation services may be used), and this must be **noted on the consent form**.

Completion of Consent Form

As soon as the parent(s) decide that their baby may participate in the trial, the **Consent Form** should be completed, and the baby randomised.

Whenever the baby's father signs the consent form, please ensure that the mother countersigns, as we need the mother's agreement to access her medical records. **If mother signs the consent form first, there is no obligation to collect the father's signature**, although the 2nd signature space provided can be used for this purpose**.**

Important points on completing the consent form

1) Please use the clipboard provided when the Consent Form is completed to ensure that the carbon copies are of good quality
2) Add participant's Study ID and NHS/CHI number to the consent form following randomisation
3) Please ensure the Parent **initials** all applicable boxes (not ticks) and then Prints, Signs and Dates the 'Name of Parent/Guardian' section. **NOTE: The date section should NOT be pre-populated for the parent**
4) The person taking the consent should also Print, Sign and Date in the 'Name of person taking consent' boxes.

5) There are **three coloured copies** of the **Consent Form**. **Remember** to ensure that any signatures/initials transfer through to the subsequent duplicate sheets, and add the Study ID and NHS/CHI number before separating as follows:
    a. original: scan and email to AZTEC@Cardiff.ac.uk. Please use an encrypted message as provided by your NHS organisation. Or, fax to the trial-specific number: 029 2251 9700. Then, place in the baby's clinical notes together with a copy of the **Parent Information Leaflet.**
    b. a copy to the **Investigator Site File**
    c. a copy to a parent

N.B. If the carbon copies are poor quality please photocopy the original consent form (top sheet) for the site file and parents.

It is important that clinical staff keep in contact with families throughout the baby's time in the trial to ensure that they understand the protocol and remain happy for their baby's continued participation.

Confirm eligibility before randomisation

Ensure the clinical assessment of trial eligibility is documented by a medically-qualified professional (who is listed on the Delegation Log) within the medical notes. An example statement is '**This baby meets the inclusion criteria and none of the exclusion criteria and is therefore eligible for entry into the AZTEC trial**'. Labels are provided in the document box to facilitate this process.

Contact details form

Please also complete a **Contact Details Form** on the eCRF if the parents have consented to follow-up contact.

Randomisation

Randomisation should be carried out prior to the intervention being given (refer to **Guidance Sheet 4: Randomisation**). **Remember** to add the Study ID to the consent form.