Guidance Sheet 3:
Notes on Informed Consent

AZTEC
Azithromycin Therapy for Chronic Lung Disease
CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
Centre for Trials Research
Canolfan Ymchwil Treialon

This guidance sheet provides a general guide to the process for taking informed consent for participation in the AZTEC trial.

General Guidance

- Introduce self (e.g. neonatal research nurse working within a research team)
- We have a trial your baby is eligible for. Is research something you are interested in? Would you like to know more?
- COMPLETELY VOLUNTARY, DO NOT HAVE TO TAKE PART AND CAN WITHDRAWAT ANY TIME
- Trial has been through ethics committee and drugs regulatory authority (MHRA), is funded by the NIHR HTA Programme and sponsored by Cardiff University
- Parent Information Leaflet (PIL) – give the parents a copy of the PIL for them to read
- Parents should be given adequate time to consider whether to take part. Allow sufficient time for parent(s) to consider their decision and arrange a follow-up meeting to answer questions. Sometimes several meetings are needed.

Recruitment

- Eligible babies born less than 30 weeks' gestation at risk of CLD
- Treatment to start within 3 days after birth, sooner if possible
- Other exclusion criteria include:
    - Exposure to another systemic macrolide antibiotic (not maternal)
    - Presence of major surgical or congenital abnormalities (not including patent ductus arteriosus or patent foramen ovale)
    - Contraindication to azithromycin
    - Participation in another trial that would preclude baby from inclusion in AZTEC
- Senior clinician to sign in notes to document inclusion in the trial to be appropriate

Study Aim/Background

- The trial your baby is eligible for is known as the AZTEC Trial and is looking at the effectiveness of azithromycin (an antibiotic) in treating babies at risk of lung problems
- At present, many preterm babies needing help with their breathing are at risk of developing CLD

- Azithromycin treats infections, and inflammation (soreness/redness) which may contribute to the development of CLD
- The aim of this study is to see whether using azithromycin can help babies' lung problems and reduce rates of CLD

What will happen if your baby participates?

- The trial is known as a Randomised Control Trial or RCT
- It is looking at an Investigational Medicinal Product or IMP. For this trial we are using azithromycin or what is known as an inactive placebo. The placebo is just water and has no active ingredients
- You will be asked to sign a consent form. As the study involves looking at the mother's medical records, we will ask the mother specifically to provide consent
- Your baby will be randomly allocated by a computer system to receive either azithromycin or the placebo
- The azithromycin or placebo will be administered to your baby intravenously (into a vein).
- The study is also blinded, so this means we do not know which drug your baby has received. This is to prevent bias in the analysis. If there are any emergencies, it is possible for staff to find out which drug your baby was given
- Azithromycin or placebo will be given to your baby once a day for 10 days
- Babies will be in the trial until they reach what would have been the 36th week of pregnancy (or discharge if this is sooner)
- Babies will be routinely monitored for this time period. Routine monitoring will include recording weight, head circumference, other medications, blood pressure etc.
- Your baby may have one additional assessment called an 'oxygen reduction test'. This is to establish whether your baby still needs additional oxygen when he/she reaches what would have been the 36th week of pregnancy or at discharge if this is sooner
- Consent will also be requested to look at how azithromycin works in the lungs
    - This involves collecting some mucus sucked up from your baby's breathing tube or nostrils, and some poo from their nappy

  - These would be collected up to 4 times (lung sample), and up to 3 times (poo sample) over a 21-day period (as long as the baby is not transferred or discharged)
  - Where possible the tiny samples are taken at the time of routine procedures and will not cause your baby any additional discomfort, harm or distress
- The samples will be sent to Cardiff University for analysis
- The samples may be kept by Cardiff University for use in other laboratory studies investigating preterm birth and the effectiveness of azithromycin. Consent for retention of samples is OPTIONAL.

Recruitment Plan

- Plan to recruit 800 babies over around 30 months. Trial started in 2019
- Approximately half the babies to receive azithromycin and half to receive placebo in randomised groups
- Possible advantages and disadvantages to taking part
  - Disadvantages to taking part may include side effects from the azithromycin.
  - However, previous use of this azithromycin has suggested that this dose is not associated with significant side effects
- We are not aware of any other risks for your baby in taking part in the study, and all babies who participate will be monitored very closely throughout the study by the staff on the Neonatal Intensive Care or Special Care Unit

Results

- Results will help us understand how whether azithromycin can help premature babies' lung function
- We will publish the results of our study in a medical journal so other clinicians/researchers can use them to help with treating pain
- We will publish a summary of the results on the trial website
- If you would like a copy of the full journal article, you can request this from the Centre for Trials Research, Cardiff

Other

- We also read babies' and mothers' notes to gather information on birth weight, gestation, age and any relevant past medical history. This is then recorded on a secure online system
- Sections of medical records may be looked at by the individuals from the Sponsor, MHRA, the CTR or the host NHS organisation
- NHS digital, or a named derivative, and other central UK NHS bodies will be used to keep in touch with and provide information about your baby's health status
- Each baby is given a study specific number and will be referred to using only this to help provide anonymity
- All relevant medical information will be kept securely
- Personal identifiable data will be treated confidentially and according to UK legislation
- If parents choose not to enter the trial, their baby will receive the same care that other babies receive
- When going back for consent after the initial information has been given – CHECK PARENTS HAVE READ AND UNDERSTOOD THE LEAFLET. Get them to run through what they think is involved in the study and fill in any missing information
- Run through the consent form with parents if needed
- Mother and father can sign consent form if parents are married or if the Father is/has:
    - married to the mother
    - listed on birth certificate
    - parental responsibility granted through a court order or parental responsibility agreement
    - If the father signs, this must be counter-signed by the mother as the study involves looking at the mother's medical information
- Ensure consent form completed accurately:
    - Full names of parent(s) and health professional is clearly recorded
    - Dates are fully completed for both parent and Health Professional
    - Parent name and date is not pre-populated by Health Professional
    - Parent has **initialled** each box

- Ensure that the consent form is completed using a clipboard and that the carbon copies of the consent form are legible. If not legible, photocopy the top copy and provide one to the parents, and one for the Investigator Site file. The original should per emailed/faxed to the CTR before being placed in the babies notes (**see guidance sheet 2**)
- Ensure that a Contact Details Form has also been completed on the eCRF (if the parent(s) consent to follow-up)

TRANSLATORS

If a translator is used to explain the study and obtain informed consist, 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**.

Any final questions? Remind them they CAN WITHDRAWAT ANY TIME and participation is VOLUNTARY.