TINN2: TREAT INFECTION IN NEONATES 2 AZITHROMYCIN FOR THE PREVENTION OF BRONCHOPULMONARY DYSPLASIA IN PRETERM NEONATES

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Background: In neonates, pulmonary Ureaplasma colonization, and inflammation may play a role in BPD development, a multifactorial disease of prematurity. The macrolide antibiotic azithromycin may be effective in reducing the severity of BPD as it is active against Ureaplasma and has anti-inflammatory properties.

Objectives and clinical trial design: Therefore, the TINN2-project (www.tinn2-project.org) was submitted and financed by the FP7 program in order to evaluate azithromycin in neonates and obtain a PUMA. The TINN2 Pediatric Investigation Plan has been approved by the PedCo in January 2013.

Within the PIP, the randomised, double-bind, placebo-controlled trial was designed to assess the efficacy of azithromycin in increasing the rate of survival without BPD in preterm infants of ≤28 weeks gestation ventilated within 48 hours of birth. The trial will include 810 preterm neonates, born at ≤28 weeks of gestation requiring respiratory support within 12 hours of birth will be recruited. The drug will be given at the daily dose of 10mg/kg for 10 days.

Among the main secondary objectives the trial will assess changes in the overall neonatal mortality rate, safety and pharmacokinetics of azithromycin, pulmonary colonisation by Ureaplasma, and Ureaplasma resistance to treatment.

Expected outcomes and potential implications: TINN2 will provide the required information on the pharmacokinetics, efficacy and safety, of azithromycin in the newborn to apply for a PUMA.

TINN2 currently benefits from various paediatric drug evaluation initiatives across Europe, including the ongoing TINN1-project consolidating a network of units with experience in clinical research that will be used for additional drug evaluation in neonates.