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Prophylactic fluconazole is effective in preventing fungal colonisation and infection in preterm neonates: a multicentre, randomised trial in Italy

Submission date
19/09/2006

Registration date
25/09/2006

Last Edited
19/09/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
To evaluate the efficacy of fluconazole prophylaxis in prevention of fungal colonisation and infection (colonisation by Candida spp., or invasive infection caused by Candida spp.) in preterm very low birth weight (i.e., less than 1500 g at birth) infants in Neonatal Intensive Care Units (NICUs).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board of the Fondazione Crescere Insieme al Sant'Anna-ONLUS approved of the study on the 15/04/2004. The Fondazione is a Charity and Scientific Foundation of the Sant' Anna Hospital Institution.

Each participating Institution reviewed the protocol and was notified of the Fondazione's approval:
1. Policlinico Umberto I^ of Rome
2. Carlo Poma Hospital of Mantua
3. Mangiagalli Hospital of Milan
4. S. Matteo Hospital of Pavia
5. Arcispedale of Reggio Emilia
6. Fatebenefratelli Hospital of Benevento
7. Department of Pediatrics, University of Messina
8. Department of Pediatrics, University of Bologna

Study design
Multicentre, prospective, randomised, double-blind, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Neonatal fungal infection

Interventions
The regimens in the two intervention groups was 6 and 3 mg/kg of fluconazole (DIFLUCAN®; Pfizer Italia S.p.A.; Latina/Roma; Italy) every third day for the first two weeks, then every other day.

Six weeks (in infants with birth weight less than 1000 g, i.e. Extremely Low Birth Weight [ELBW]) and four weeks (in the infants with birth weight 1001 to 1500 g) were chosen as the duration of therapy on the basis of the currently published data, unless earlier discharge or need for systemic antifungal therapy due to the onset of proven or presumed invasive fungal infection.

Prophylaxis started from day of life three via a single dose intravenously or orally (via orogastric tube), depending on the availability of a venous line and/or the tolerance of oral feeding. Infants in the control group received placebo (1 ml saline) in the same way.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fluconazole prophylaxis

Primary outcome measure
The primary objective of the study was to evaluate the effectiveness of 3 and 6 mg/kg fluconazole compared with placebo in the prevention of Candida colonisation and infection in the preterm very low birth weight neonates admitted to the participant NICUs.

Secondary outcome measures
1. Assessment of the incidence of Gram-positive and Gram-negative sepsis
2. Mortality (overall and Candida-attributable)
3. Rate of progression from colonisation to infection
4. Necrotising enterocolitis
5. Ligation of patent ductus arteriosus
6. Threshold retinopathy of prematurity requiring surgery
7. Severe (grade 3-4) intraventricular haemorrhage
8. Bronchopulmonary dysplasia
9. Alteration of liver function as measured by serum AST, ALT, direct bilirubin and gamma-Glutamyl Transferase (gGT) values at baseline and at the end of all administrations

Overall study start date
01/05/2004

Completion date
31/07/2005

Eligibility

Key inclusion criteria
All neonates with birth weight less than 1500 g (i.e. Very Low Birth Weight [VLBW]) born within the study period, whether at one of the eight Institutions or elsewhere, were eligible for the study.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
267

Key exclusion criteria
1. Parental refusal
2. Admission after 72 hours of life
3. Death prior to 72 hours of life
4. Liver failure (defined as three-fold elevation of Aspartate Aminotransferase [AST] and/or Alanine Aminotransferase [ALT] above the reference values)

Date of first enrolment
01/05/2004

Date of final enrolment
31/07/2005

Locations

Countries of recruitment
Italy

Study participating centre
Neonatology and Hospital NICU
Torino
Italy
10126

Sponsor information

Organisation
Saint Anna Foundation (Fondazione Crescere Insieme al Santa Anna [ONLUS]) (Italy)

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Sponsor type
Charity

ROR
https://ror.org/00k065b17

Funder(s)

Funder type
Industry

Funder Name
Pfizer Italia S.p.A. (Italy) - supplied study drugs, provided financial support with a grant, but was not involved in the concept, design, enrolment, data collection, analysis and interpretation of its results.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		01/01/2006		Yes	No
Results article		14/06/2007		Yes	No