

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

Submission date 19/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/09/2007	Condition category Neonatal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paolo Manzoni

Contact details
Neonatology and Hospital NICU
C. Spezia 60
Torino
Italy
10126
+39 (0) 113 134 304
manzonipaolo@hotmail.it

Additional identifiers

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

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

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?
Results article		14/06/2007		Yes	No
Other publications		01/01/2006		Yes	No