

# A prospective randomised phase III trial of early hospital discharge versus standard inpatient management of cancer patients with low-risk febrile neutropenia receiving oral antibiotics

<b>Submission date</b> 03/07/2006	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/08/2006	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/11/2012	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.orange.bham.ac.uk>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Ernest Marshall

### Contact details

Clatterbridge Centre for Oncology NHS Trust  
Clatterbridge Road  
Bebington  
Wirral  
Merseyside  
United Kingdom  
CH63 4JY  
+44 (0) 151 334 1155  
[emarshall@nhs.net](mailto:emarshall@nhs.net)

## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

NCT00445497

**Secondary identifying numbers**

MX3006

## **Study information**

**Scientific Title**

**Acronym**

ORANGE, Oral Antibiotics for Neutropenic Sepsis Giving Early Hospital Discharge

**Study objectives**

To determine, in the setting of the management of patients with solid tumours and lymphoma, whether in-patients treated with oral antibacterial therapy for neutropenic sepsis and at low risk for complications from infection can be identified for early discharge using the criteria of symptomatic improvement and temperature less than 37.8°C irrespective of neutrophil recovery.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

North West MREC approved on 30/05/2006 (ref. no.: 06/MRE08/31).

**Study design**

Two arm randomised 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**

Neutropenic sepsis

**Interventions**

Treatment with oral Ciprofloxacin 750 mg twice daily and Co-amoxycylav 625 mg three times a day, and daily temperature readings. For the research arm patients will be discharged home early.

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Ciprofloxacin and Coamoxycylav

## **Primary outcome measure**

1. Total number of days of hospitalisation (including unplanned readmission)
2. Incidence of serious adverse events

## **Secondary outcome measures**

1. Incidence of treatment failure as defined by the necessity for change in antibacterial therapy
2. Incidence of unplanned readmissions
3. Patient acceptability
4. Toxicity attributed to oral antibiotic therapy
5. Costs to health service

## **Overall study start date**

01/07/2006

## **Completion date**

01/07/2009

## **Reason abandoned (if study stopped)**

Participant recruitment issue

# **Eligibility**

## **Key inclusion criteria**

1. No previous participation in ORANGE for neutropenic episode
2. Undergoing cytotoxic chemotherapy to treat solid tumours or lymphoma
3. An Absolute Neutrophil Count (ANC) of more than or equal to  $0.5 \times 10^9$  l. Patients are also eligible if their ANC is between  $0.5 \times 10^9$  l but anticipated to fall to less than or equal to  $0.5 \times 10^9$  l within 24 hours of entry into the study
4. A temperature of more than or equal to  $38.5^\circ\text{C}$  on a single measurement or more than  $38.0^\circ\text{C}$  on more than one occasion, at least one hour apart, one of which could be measured by the patient prior to admission
5. Patients with neutropenic fever (defined as above) at low risk of complications according to the Multinational Association of Supportive Care in Cancer (MASCC) prognostic index score more than or equal to 21
6. Age is 18 years or over
7. Compliant patient and appropriate for early discharge in the opinion of the investigator. All patients are required to have a responsible adult living with them who would be prepared to act

as a carer if the patient were eligible for early discharge. Either patient or carer should be able to read a thermometer

8. Able to tolerate oral medication

9. Written informed consent obtained

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

400 registered; 320 randomised

**Key exclusion criteria**

1. Neutropenic fever judged by the clinician to be at high risk of complications
2. Allergies to oral antibiotics or penicillin used in ORANGE
3. Clinical condition necessitates intravenous fluid support
4. Central venous catheter associated infection or evidence of infection thought in the opinion of the investigator not to be adequately treated by the study antibiotics
5. Previous bone marrow transplant or peripheral blood stem cell transplant
6. Associated co-morbidity that requires hospitalisation and management
7. Received antibiotic therapy, including prophylactic antibiotics, within the last 72 hours (prophylactic septrin for pneumocystis, acyclovir or antifungals are acceptable)
8. Receiving Granulocyte Colony Stimulating Factor (G-CSF)
9. Known Human Immunodeficiency Virus (HIV) positive
10. Patients treated for leukaemia

**Date of first enrolment**

01/07/2006

**Date of final enrolment**

01/07/2009

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Clatterbridge Centre for Oncology NHS Trust**  
Merseyside  
United Kingdom  
CH63 4JY

## **Sponsor information**

### **Organisation**

University of Birmingham (UK)

### **Sponsor details**

Research and Enterprise Services  
Aitcheson Building  
Birmingham  
England  
United Kingdom  
B15 2TT  
+44 (0) 121 414 3898  
res-ent@bham.ac.uk

### **Sponsor type**

University/education

### **Website**

<http://www.res.bham.ac.uk/>

### **ROR**

<https://ror.org/03angcq70>

## **Funder(s)**

### **Funder type**

Charity

### **Funder Name**

Clinical Trials Advisory & Awards Committee (CTAAC) Ref: C1810/A4818

## **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