

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00445497

Protocol serial number

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).

Primary study design

Interventional

Study design

Two arm randomised controlled trial

Study type(s)

Treatment

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 Coamoxyclav

Primary outcome(s)

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

Key secondary outcome(s)

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

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 0.5×10^9 l. Patients are also eligible if their ANC is between 0.5×10^9 l but anticipated to fall to less than or equal to 0.5×10^9 l within 24 hours of entry into the study
4. A temperature of more than or equal to 38.5°C on a single measurement or more than 38.0°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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Clatterbridge Centre for Oncology NHS Trust

Merseyside

United Kingdom

CH63 4JY

Sponsor information**Organisation**

University of Birmingham (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

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes