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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

Registration date
17/08/2006

Last Edited
05/11/2012

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Infections and Infestations

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

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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-amoxyclav 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 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 x 10^9 l. Patients are also eligible if their ANC is between 0.5 1 x 10^9 l but anticipated to fall to less than or equal to 0.5 x 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

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
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Sponsor information

Organisation
University of Birmingham (UK)

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Sponsor type
University/education

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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