ISRCTN49693355 https://doi.org/10.1186/ISRCTN49693355

A randomised prospective double-blind, placebo controlled trial of prophylactic oral levofloxacin following chemotherapy for lymphoma and solid tumours

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 28/10/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00005590

Protocol serial number
SIGNIFICANT

Study information

Scientific Title
A randomised prospective double-blind, placebo controlled trial of prophylactic oral levofloxacin following chemotherapy for lymphoma and solid tumours

Study objectives
Added 07/08/09:
Giving antibiotics may be effective in preventing or controlling early infection in patients receiving chemotherapy for solid tumors or lymphoma. It is not yet known if levofloxacin if effective in preventing infection.The aim of this trial is to determine the effectiveness of levofloxacin in preventing infection in patients receiving chemotherapy for solid tumors or lymphoma.

As of 07/08/09 this record was extensively updated. All updates can be found under the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Multicentre randomised double blind placebo controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Breast, testis, lung (small cell), lymphoma (Hodgkins), lymphoma (non-Hodgkins)

Interventions
1 x 500 mg tablet of placebo or levofloxacin/day for seven days. Start on day eight for 21-day cycles or on day 15 for 28-day cycles.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Levofloxacin

Primary outcome(s)

Added 07/08/09:
Rate of clinical infection

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/2003

Eligibility

Key inclusion criteria
1. Adult who has given informed consent
2. Solid tumour or lymphoma
3. First cycle of anti-neoplastic chemotherapy
4. Anticipated neutrophil nadir <0.5 x 10^9/l
5. Normal serum creatinine or creatinine clearance >40 ml/min
6. Adequate contraceptive measures in place

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Human Immunodeficiency Virus (HIV) positive
2. Pregnant or breast feeding
3. Epileptic
4. Planned granulocyte colony-stimulating factor (GCSF) or stem cell support
5. Currently taking antibacterial therapy or prophylaxis
6. History of adverse effects caused by fluoroquinolone agent
7. Previous participation in the Significant trial

Date of first enrolment
03/08/1999

Date of final enrolment
31/12/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/09/2005		Yes	No
Plain English results			28/10/2021	No	Yes