

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/10/2021	Condition category Cancer	<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 - -

Contact details

UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00005590

Secondary identifying numbers

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 is 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

Study design

Multicentre randomised double blind placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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 measure

Added 07/08/09:

Rate of clinical infection

Secondary outcome measures

Not provided at time of registration

Overall study start date

03/08/1999

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 $<0.5 \times 10^9/l$
5. Normal serum creatinine or creatinine clearance >40 ml/min
6. Adequate contraceptive measures in place

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

A total of 1,500 patients (750 per arm) will be accrued for this study within 3 years (added 07/08/09)

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

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Cancer Research UK (CRUK) (UK)

Sponsor details

PO Box 123

Lincoln's Inn Fields

London

United Kingdom

WC2A 3PX

+44 (0)207 317 5186

kate.law@cancer.org.uk

Sponsor type

Charity

Website

<http://www.cancer.org.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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	results	08/09/2005		Yes	No
Plain English results			28/10/2021	No	Yes