

A study of the efficacy of a combination of chlorambucil and lomustine and etoposide (CLE 56) for absolute refractory prostate cancer

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/10/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-phase-2-trial-of-lomustine-and-chlorambucil-in-prostate-cancer-which-is-no-longer-responding-to-hormone-treatment>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

Does a combination of lomustine, chlorambucil and etoposide improve the response rate and re-exposure to hormone therapy following failure of chemotherapy will be formally assessed with re-introduction of hormones sequentially following the failure of chemotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Chlorambucil, lomustine and etoposide (CLE 56). If one response is seen amongst the first 14 patients the target will be increased to 23. If one or more response is seen, consideration will be given to increasing numbers to 40.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Chlorambucil, lomustine, etoposide (CLE 56)

Primary outcome measure

1. To establish response rates and time to treatment failure of the regime CLE 56
2. To assess quality of life (QOL)
3. To establish effect on survival
4. To establish whether a hormone-free interval during chemotherapy leads to re-induction of endocrine therapy

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2003

Completion date

31/12/2004

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Male

Target number of participants

40

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/02/2003

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Cancer Services

Romford, Essex

United Kingdom

RM3 0BE

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Barking, Havering and Redbridge Hospitals NHS Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	17/01/2005		Yes	No