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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 05/10/2012	**Condition category** Cancer	

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
Dr Jonathan Shamash

Contact details
Cancer Services
Oldchurch Hospital
Romford, Essex
United Kingdom
RM3 0BE
+44 (0)1708 517980
jonathan.shamash@bartsandthelondon.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0020121021

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