ISRCTN50615178 https://doi.org/10.1186/ISRCTN50615178

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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
05/10/2012

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

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

Completion date

31/12/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Male

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
United Kingdom

England

Study participating centre
Cancer Services
Romford, Essex
United Kingdom
RM3 0BE

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Barking, Havering and Redbridge Hospitals NHS Trust (UK)

Results and Publications

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