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A randomised trial of chlorambucil versus fludarabine as initial therapy of Waldenstrom's macroglobulinaemia and splenic lymphoma with villous lymphocytes

Submission date 06/02/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/03/2004	**Overall study status** Completed	
Last Edited 19/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.waldenstroms.org/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00608374

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised trial of chlorambucil versus fludarabine as initial therapy of Waldenstrom's macroglobulinaemia and splenic lymphoma with villous lymphocytes

Study objectives
Added as of 20/05/2008:
Rationale:
Drugs used in chemotherapy, such as chlorambucil and fludarabine, work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. It is not yet known whether chlorambucil is more effective than fludarabine in treating Waldenström macroglobulinemia, splenic lymphoma, or lymphoplasmacytic lymphoma.

Purpose:
This randomised phase III trial is studying chlorambucil to see how well it works compared with fludarabine as first-line therapy in treating patients with previously untreated Waldenström macroglobulinemia, splenic lymphoma, or lymphoplasmacytic lymphoma.

Objectives:
Compare the efficacy of first-line therapy comprising chlorambucil versus fludarabine phosphate in patients with previously untreated Waldenström macroglobulinemia, splenic lymphoma with villous lymphocytes, or non-IgM lymphoplasmacytic lymphoma.

Please note that, as of 20/05/2008, Australia was added to the list of countries of recruitment (previously United Kingdom only).

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Waldenstrom's macroglobulinaemia and related disorders

Interventions
Current interventions as of 20/05/2008:
This is a multicentre study. Patients are stratified according to disease (Waldenström macroglobulinemia versus splenic lymphoma with villous lymphocytes vs non-IgM lymphoplasmacytic lymphoma). Patients are randomised to 1 of 2 treatment arms.

Arm I: Patients receive oral chlorambucil on days 1 - 10. Treatment repeats every 28 days for up to 12 courses in the absence of disease progression or unacceptable toxicity.
Arm II: Patients receive fludarabine phosphate orally or IV on days 1 - 5. Treatment repeats every 28 days for 3-6 courses in the absence of disease progression or unacceptable toxicity.
Patients undergo quality of life assessment at baseline.

Previous interventions:
Chlorambucil versus fludarabine

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Added as of 20/05/2008:
1. Response to therapy (complete and partial response rates)
2. Duration of response

Secondary outcome measures
Added as of 20/05/2008:
1. Improvement in haematological parameters
2. Toxicity
3. Quality of life as assessed by the European Organisation for Research and Treatment of Cancer Quality of Life-30 questionnaire
4. Survival

Overall study start date
01/06/2006

Completion date

30/06/2009

Eligibility

Key inclusion criteria
All patients with previously untreated disease who require therapy as judged by their primary physician and who satisfy the eligibilty criteria.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Added as of 20/05/2008: 400

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2006

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Australia

England

United Kingdom

Study participating centre
Haematology Department
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Sponsor information

Organisation
Taunton and Somerset NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02y5f7327

Funder(s)

Funder type
Industry

Funder Name
Schering Healthcare Ltd (UK) - provided educational grant towards the website construction /administration costs and data management

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?
Plain English results	protocol			No	Yes

Protocol article	results	01/03/2005	Yes	No
Results article		20/01/2013	Yes	No