

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

<b>Submission date</b> 06/02/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/03/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.waldenstroms.org/>

## 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**

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 eligibility 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)

## Sponsor details

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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?
<a href="#">Plain English results</a>	protocol			No	Yes

[Protocol article](#)

[Results article](#)

	01/03/2005	Yes	No
results	20/01/2013	Yes	No