

CLL4 - ENTRY FORM [A]

Please return completed form to:

FREEPOST RLUJ-UUUU-UUAC, CTSU, Richard Doll Building, Old Road, Headington, Oxford OX3 7LF
or Fax: +44-(0)1865-743986

Please complete this section before phoning for randomisation

Consultant Hospital

Patient's full name Sex

Date of birth...../...../..... Date of diagnosis...../...../.....

Hb (g/dl) Platelets ($\times 10^9/l$) BM lymphocytes%

Any enlargement of: Spleen Yes No

Liver Yes No

Lymph nodes in: Neck Yes No

Axillae Yes No

Groin Yes No

Please telephone CTSU for randomisation (+44-(0)1865-765615) and note the information given:

Stage A B C CLL trial number

Treatment allocated: Chlorambucil Fludara Fludara plus Cyclo

Date phoned/...../.....

WBC ($\times 10^9/l$) Lymphocytes% $\beta 2$ microglobulinmg/l

DAG test: +ve -ve not done

LDH: Patient Normal range

For stage A, indicate features of progression:

Lymphocyte doubling <12 months Yes No

Increase in nodes/spleen, etc Yes No

B symptoms Yes No

Drop in Hb/plat/PMN Yes No

Please provide patient with QOL questionnaire.

CLL4 - FIRST TREATMENT FORM [B]

Please return after completion of first treatment (about 6mths (FDR) or one year (ChI)) to:
FREEPOST RLUJ-UUUU-UUAC, CTSU, Richard Doll Building, Old Road, Headington, Oxford
OX3 7LF or
FAX: +44-(0)1865-743986

Consultant Hospital

Patient's full name CLL trial number

Treatment given Chlorambucil Fludara Fludara plus Cyclo Oral or IV Fludara

Date started/...../..... No. of courses

Was full dose given? Yes No Date completed/...../.....

Response Date of best response/...../..... All data recorded in this section should be at this date

Best response CR NPR PR NR PD Not assessable

Hb (g/dl) Platelets ($\times 10^9/l$)

WBC ($\times 10^9/l$) Lymphocytes% Neutrophils%

BM lymphocytes% BM biopsy? Yes No

DAG test +ve -ve not done

Any enlargement of: Spleen Yes No Liver Yes No

Lymph nodes in: Neck Yes No Axillae Yes No

Groin Yes No

TOXICITY DURING THIS TREATMENT PERIOD

Neutropenia ($<1 \times 10^9/l$) Yes No Non-haematological (with WHO toxicity grade, see back of form)

Thrombocytopenia ($<50 \times 10^9/l$) Yes No Grade

Haemolytic anaemia Yes No Nausea/vomiting

Alopecia

Number of days in hospital Mucositis

Diarrhoea

Number of febrile episodes requiring antibiotics Other Yes No

If Yes specify:

Type Grade

PATIENT STATUS

Performance status (WHO; see back of form) Vital status Alive Dead

If died: Date of death/...../..... Cause of death

Autopsy done? Yes No

WHO TOXICITY GRADING AND PERFORMANCE STATUS

WHO toxicity grading

Grade	1	2	3	4
Nausea / Vomiting	Nausea	Transient vomiting	Vomiting requiring therapy	Intractable vomiting
Alopecia	Minimal hair loss	Moderate, patchy alopecia	Severe alopecia	Total alopecia
Oral	Soreness / erythema	Erythema, ulcers, can eat solids	Ulcers, requires liquid diet	Feeding not possible
Diarrhoea	Transient < 2 days	Tolerable but > 2 days	Intolerable, requiring therapy	Haemorrhagic dehydration
Cardiac Function	Asymptomatic, but abnormal cardiac sign	Transient symptomatic dysfunction, no therapy required	Symptomatic dysfunction, responsive to therapy	Symptomatic dysfunction, not responsive to therapy

WHO Performance Status

Grade 0 - Able to carry out all normal activity without restriction.

Grade 1 - Restricted in physically strenuous activity but able to walk and do light work.

Grade 2 - Able to walk and capable of all self-care, but unable to carry out any work. Up and about more than 50% of waking hours.

Grade 3 - Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.

Grade 4 - Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.

CLL4 - FOLLOW-UP FORM [C]

Please complete this form yearly for the first 5 years from entry and return to:
FREEPOST RLUJ-UUUU-UUAC, CTSU, Richard Doll Building, Old Road, Headington, Oxford OX3 7LF
or
Fax: +44-(0)1865-743986

Date/...../.....

Consultant Hospital

Patient's full name CLL trial number

Disease status

- Never responded Stable disease
 Relapse (progression requiring therapy)

If progression: Date when documented/...../.....

- Evidence of progression: Downward trend Hb/plt
 Lymphocyte doubling time <12 months
 Progressive organomegaly

Have you initiated further therapy? Yes No

- If yes, treatment: Chlorambucil Fludara
 Fludara plus Cyclo CHOP
 Other. Specify
-

Vital status

Alive Dead

If died: Date of death/...../..... Cause of death

Autopsy done? Yes No

CLL4 - 2ND LINE TREATMENT FORM [D]

Please complete this form for all patients treated with 2nd line therapy (different from initial treatment) at the end of this phase of treatment, and return to:
FREEPOST RLUJ-UUUU-UUAC, CTSU, Richard Doll Building, Old Road, Headington, Oxford OX3 7LF
or Fax: +44-(0)1865-743986

Date/...../.....

Consultant Hospital

Patient's full name CLL trial number

Second randomisation

Was second randomisation done? Yes No

If No, reason Patient refusal
 Clinical, please specify
 Other, please specify

If Yes, was recommended treatment given? Yes No

If No, reason: Patient refusal
 Clinical, please specify
 Other, please specify

Treatment given

CHOP Fludara Fludara plus Cyclo

Other. Please specify

Date initiated/...../.....

No. of courses given

Response CR NPR PR NR PD Not assessable

Vital status

Alive Dead

If died: Date of death/...../..... Cause of death

Autopsy done? Yes No