Clinical trial results:
CLARET: CLL Levels following Alemtuzumab in Responders to Early Therapy: A randomised, phase III trial to assess alemtuzumab consolidation therapy in patients with chronic lymphocytic leukaemia (CLL) who have responded to previous therapy.

Summary

EudraCT number	2008-003012-35
Trial protocol	GB
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	29 March 2020
First version publication date	29 March 2020
Summary attachment (see zip file)	Never opened to recruitment statement (LTHT_Suspension Statement.docx)

Trial information

Trial identification

Sponsor protocol code	HM07/8281

Additional study identifiers

ISRCTN number	ISRCTN63375144
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Leeds
Sponsor organisation address	Worsley Building, Leeds, United Kingdom, LS2 9JT
Public contact	Clare Skinner, University of Leeds, c.e.skinner@leeds.ac.uk
Scientific contact	Clare Skinner, University of Leeds, c.e.skinner@leeds.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	18 September 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

The principal research objective is to compare consolidation therapy with alemtuzumab against no consolidation therapy with respect to progression free survival.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 September 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Trial was withdrawn before opening, so no patients were recruited to the trial.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Main Trial Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

N/A

Arms

Arm title	consolidation therapy with alemtuzumab

Arm description: -

Arm type	Experimental
Investigational medicinal product name	alemtuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

participants were to receive alemtuzumab injections given under the skin (subcutaneously) 3 times a week for 6 weeks

Number of subjects in period 1	consolidation therapy with alemtuzumab
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Main Trial Period

Reporting group description: -

Reporting group values	Main Trial Period	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	consolidation therapy with alemtuzumab

Reporting group description: -

Primary: progression-free survival of alemtuzumab patients

End point title	progression-free survival of alemtuzumab patients[1]

End point description:

this trial was discontinued with no participants enrolled in the trial.

End point type	Primary

End point timeframe:

this trial was discontinued with no participants enrolled in the trial.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification:
this trial was discontinued with no participants enrolled in the trial.

End point values	consolidation therapy with alemtuzumab			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: yes/no				

Notes:

[2] -
this trial was discontinued with no participants enrolled in the trial.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: n/a- trial never opened to recruitment	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: this trial was discontinued with no participants enrolled in the trial.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

this trial was discontinued with no participants enrolled in the trial.

Notes: