

An overview of current CLL clinical trials in Europe

CENTER/GROUP	TRIAL	SITUATION	CONTACT PERSONS	OTHER REMARKS
Europewide				
Nordic-Dutch-Polish-Czech-Israeli	HOVON68 CLL Trial: AFC vs FC front-line in CLL biological high-risk	Ongoing, 225 of 300 planned patients accrued. Expected completed 2010	Dr Christian Geisler christian.geisler@rh.dk Phone: +45 3545 1146	(Alemtuzumab low-dose)
France				
Sponsor = ROCHE GA101 in CD20+ malignancies	NCT00517530: phase I/II of the anti-CD20 GA101 (R7159) in relapsed/refractory CD20+ CLL patients	Phase I and II completed (France + Germany)	pavel.pisa@roche.com	
Germany				
GCLLSG CURATIVE trial	AlloSCT versus chemo or observation (PA refractory, p53, early relapse after intensive therapy (EBMT transplant indications))	At the IRB	Dr Peter Dreger Abteilung Innere Medizin V Universitätsklinikum Im Neuenheimer Feld 410 69120 Heidelberg peter.dreger@med.uni-heidelberg.de	
	First-Line therapies -CLL7 in Binet A high risk patients Deferred vs. FCR -CLL10 Phase III FCR vs. BR		Dr Michael Hallek michael.hallek@uni-koeln.de	
GCLLSG in cooperation with FCLLSG (20 centres each)	17p- First or higher line (not refractory) and F-Refractory -CLL20 (17p- or fluda refractory) Phase II	Ongoing	Dr Stephan Stilgenbauer stephan.stilgenbauer@uniklinik-ulm.de or GCLLSG webpage http://www.dcllsg.de/	

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	Cam-dexa → Campath Maintenance or Allogeneic Tx as Consolidation			
Italy				
ITALIAN MULTICENTER STUDY Coordinated by: Divisions of Hematology Niguarda Ca' Granda Hospital Milano –Molinette Hospital Torino	BENDAMUSTINE plus CAMPATH as salvage regimen (DOSE FINDING)	Ongoing	Dr Marco Montillo, Division of Hematology Niguarda Ca' Granda Hospital Milano. marco.montillo@ospedaleniguarda.it	
Division of Hematology Niguarda Ca' Granda Hospital Milano	LENALIDOMIDE plus CAMPATH as consolidation in responder pts after a salvage regimen (DOSE FINDING)	Ongoing	Dr Marco Montillo, Division of Hematology Niguarda Ca' Granda Hospital Milano. marco.montillo@ospedaleniguarda.it	
Israel				
Israel CLL Study Group (ICLLSG)	ICLLSG 001 Phase II low dose FC in elderly CLL	Starting Dec 2009/Jan 2010 50 patients Expected completion 2012	Dr Aaron Polliack apol@cc.huji.ac.il 0972-507874362	low dose Fludara 12.5mg/m2 D1-3 Cytosan 150mg/m2 D1-3
Kaplan Medical Center Israel	NCT 00868478 Phase I-II Milatuzumab (anti CD74) for refractory CLL	April 2009 15 patients Expected completion 2012	Dr Michal Haran michal.haran@gmail.com 00972-507679598	Efficacy and dose range of antibody.
Wolfson Health Gov Israel	Phase II Fresh Frozen Plasma(FFP) and Rituximab For advanced refractory CLL	January 2009 15 patients Expected completion 2011	Dr Abraham Klepfish klepfish@zahav.net.il 00972-89472420	Analysis of Complement activating pathway

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Netherlands				
HOVON/NORDIC CLL group	HOVON 68: FC versus FCA in high risk previously untreated CLL	ongoing accrual 225 (target 300)	Dr Geisler, Dr van Oers m.h.vanoers@amc.uva.nl	
HOVON/NORDIC CLL group	HOVON 101/GSK OMB11251768:Ofatumumab vs observation in relapsed CLL in CR/PR after a maximum of 3 regimens	start end 2009	Dr van Oers m.h.vanoers@amc.uva.nl , Dr Geisler	
HOVON	HOVON 88: R-DHAP folowed by RIST alloSCT in fludarabin refractory CLL; a Phase II study	ongoing	Dr Van Gelder m.van.gelder@mumc.nl	
Spain				
Hospital Vall d'Hebron, Barcelona	Lenalimodima + Dexametasona, phase II		Dr Bosch	
United Kingdom				
NCRI CLL sub-group, UK	NCRI CLL201; Randomised Phase II in relapsed CLL; FCM vs FCM-R (n=52)	Finished, presented at international meetings but not yet published	Dr Peter Hillmen; peter.hillmen@nhs.net	
NCRI CLL sub-group, UK	NCRI CLL202 (CamFlud); Non-randomised Phase II in refractory CLL; SC Campath+fludarabine (n=50)	Finished, presented at international meetings but not yet published	Dr Peter Hillmen; peter.hillmen@nhs.net	
NCRI CLL sub-group, UK	NCRI CLL203 (RESPECT); Newly diagnosed Stage A CLL; Lenalidomide therapy for biologically poor risk (n=40)	Opening shortly	Dr Adrian Bloor/Steve Devereux	

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NCRI CLL sub-group, UK	NCRI CLL206 (CamPred); Non-randomised Phase II in p53 deleted CLL; Campath+HDMP (n=40)	Finished, presented at international meetings but not yet published	Dr Andy Pettitt	
NCRI CLL sub-group, UK	NCRI CLL207; Non-randomised Phase II of consolidation with alemtuzumab after chemotherapy; Alemtuzumab SC (n=54)	Interim analysis presented at EHA 2009; Recruitment to close end January 2010	Dr Peter Hillmen; peter.hillmen@nhs.net	
NCRI CLL sub-group, UK	NCRI CLL208; Non-randomised Phase II untreated patients with CLL considered unfit for fludarabine combinations; Chlorambucil+rituximab (n=100)	Interim analysis completed; Recruitment to complete 2009	Dr Peter Hillmen; peter.hillmen@nhs.net	Roche sponsored study
NCRI CLL sub-group, UK	ADMIRE Study; Randomised Phase II in previously untreated patients with CLL fit for fludarabine-combinations; FCR vs FCM-R (n=218)	Opened to recruitment August 2009	Dr Peter Hillmen; peter.hillmen@nhs.net	
NCRI CLL sub-group, UK	ARCTIC Study; Randomised Phase II in previously untreated patients with CLL fit for fludarabine-combinations; FCR vs FCM-miniR (n=206)	Due to open recruitment in final quarter 2009	Dr Peter Hillmen; peter.hillmen@nhs.net	
NCRI CLL sub-group, UK	NCRI CLL7 (Complement-1);	Open and currently	Dr Peter Hillmen;	International trial;

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	Phase III in previously untreated patients with CLL unfit for fludarabine-combinations; Chlorambucil vs Chlorambucil+ofafumumab (n=444)	recruiting	peter.hillmen@nhs.net	Sponsored by GSK
NCRI CLL sub-group, UK	NCRI CLL8 (CLARET); Randomised Phase III of consolidation with alemtuzumab in CLL; Alemtuzumab SC vs no therapy (n=116)	Planned to open April 2010 depending on results of CLL207	Dr Peter Hillmen; peter.hillmen@nhs.net	