Public Title	Stopping TKI in patients with CML in complete molecular remission (MR4)
Scientific Title	Multicenter prospective trial estimating the persistence of molecular remission in chronic myeloid leukemia after stopping TKI
Short Title	EuroSKI
Id KN/ELN	LN_CMLSTU_2012_494
Trialgoup	CML-Studiengruppe
Type of Trial	NIS, multicentric, single-group, prospective, open-label
Phase	N/A
Disease	Chronic myeloid leukemia(CML) Chronic Phase
Stage of Disease	Complete molecular remission (MR4)
Molecular Marker	BCR-ABL
Aim	- Evaluation of molecular relapse-free survival after stopping TKI [survival without molecular relapse defined by BCR-ABL1 > 0.1% on the IS at one time point (loss of major molecular response, MMR)] - Clinical and biological profile of complete and major molecular remission persistence - Overall and progression-free survival and the probabilities of a restart of TKI without prior molecular relapse - Patient reported QoL and symptom burden over time - Saved treatment costs / country from the time off TKI therapy considering also the more frequent PCR monitoring - Registering patients in confirmed MR4 and MR4.5 - Analysing the time to recovery of MR4 after loss of MMR
Inclusion Criteria	- CML in CP under treatment with TKI in first line or in second line because of toxicity to first line TKI or with TKI in combination - Duration of TKI treatment before enrolment at least 3 years - At least complete molecular remission MR4 (either (i) detectable disease <=0.01% BCR-ABL IS or (ii) undetectable disease in cDNA with >=10,000 ABL or >=24,000 GUS transcripts) for at least one year; at least three PCR-results with MR4 within the last year (+- 2 months) before study entry and no PCR-results > 0.01% during the same period - Before inclusion confirmation of MR4 through a EUTOS-CMR laboratory - Baseline data and documentation on treatment before study entry available - Both sexes but fertile women only if using effective contraceptive - Health insurance coverage - 18 years or older - Known baseline data at diagnosis, EURO-Score
Exclusion Criteria	- Hospitalized patients without ability to give informed consent - Adults under law protection or without ability to consent - Previous or planned allogeneic stem cell transplantation
Age	>= 18 years
Status	Closed
start of Recruitment	31.05.2012
Recruiting countries	Germany France U.K. Czech Republic

	Spain
	Italy
	Greece
	Portugal
	The Netherlands
	Poland
	Switzerland
	Austria
	Norway
	Ireland
	Finland
	Denmark
	Russian Federation
	Sweden
Target Sample Size	500
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Supporters
European LeukemiaNet
Homepage: http://www.leukemia-net.org

Other Registers
ClinicalTrials.govNCT01596114
European Clinical Trials Database - EUDRACT2011-000440-22