

Navn
CPR:

Patient nr: _____

Inklusionskriterier				
Kriterie	Beskrivelse	Ja	Nej	NA
1	Patients newly diagnosed with T-lymphoblastic (T-cell) or B-lymphoblastic precursor (BCP) leukaemia (ALL) according to the WHO-classification of Tumours of Haematopoietic and Lymphoid Tissues (Revised 4th edition 2017) and with a diagnosis confirmed by an accredited laboratory at a participating paediatric oncology or adult haematology centre.			
2	Age between > 365 days and < 46 years (one day before 46th birthday) at the time of diagnosis.			
3	Informed consent signed by parents/guardians and/or the patient according to country-specific age-related guidelines (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199234.pdf) before any study-specific activity is performed.			
4	The ALL diagnosis should be confirmed by an accredited laboratory at a participating paediatric oncology or adult haematology centre.			
5	The patient should be diagnosed and treated at a participating paediatric oncology or adult haematology centre. However, some treatment, supportive care and follow-up, as well as registration, may be delegated to a shared care centre under the supervision of a study centre.			
6	The patient should be a resident in one of the participating countries on a permanent basis or should intend to settle in a participating country, for instance by an application for asylum. Patients who are visiting the country as tourists should not be included. However, returning expatriots and patients who intend to stay at least for the duration of the treatment with primary diagnosis abroad may be included if no treatment has been administered and the diagnostic procedures are repeated at a participating centre.			
7	All sexually active female patients of childbearing potential have to have a negative pregnancy test within 2 weeks prior to the start of treatment.			
8	For each intervention/randomisation an additional set of inclusion/exclusion criteria is provided.			

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Eksklusionskriterier:				
Kriterie	Beskrivelse	Ja	Nej	NA
1	Age < 365 days at diagnosis (infant ALL). These patients will be transferred to an adequate trial for infant ALL if available.			
2	Age >45 years at diagnosis (from the 46th birthday onwards)			
3	Patients with a previous malignant diagnosis (ALL as a second malignant neoplasm - SMN). However, patients with a history of skin cancer (except melanoma) with only local treatment are eligible.			
4	Relapse of ALL.			
5	Patients with mature B-ALL (as defined by Surface Ig positivity or documented presence of one of the t(8;14), t(2;8), t(8;22) translocations and breakpoint as in B-ALL).			
6	Patients with Ph-positive ALL (documented presence of t(9;22)(q34;q11) and/or of the BCR-ABL1 fusion transcript). These patients will be transferred to an adequate trial for t(9;22) if available.			
7	ALL prone syndromes (e.g. Li-Fraumeni syndrome, germline ETV6 mutation), except for Down syndrome. Exploration for such ALL prone syndromes is not mandatory.			
8	Treatment with systemic corticosteroids (>10mg/m ² /day) for more than one week and/or any chemotherapeutic agents during the 4-week interval prior to diagnosis (pre-treatment).			
9	Pre-existing contraindications to any treatment according to the ALLTogether protocol (constitutional or acquired disease prior to the diagnosis of ALL preventing treatment according to the protocol).			
10	Any other disease or condition, as determined by the investigator, which could interfere with the participation in the study according to the study protocol, or with the ability of the patients to cooperate and comply with the study procedures.			
11	Women of childbearing potential who are pregnant at the time of diagnosis.			
12	Women of childbearing potential and fertile men who are sexually active and are unwilling to use adequate contraception during therapy. Efficient birth control is required, see section 17.7.			
13	Female patients, who are breast-feeding.			
14	Essential data missing from the registration of characteristics at diagnosis (in consultation with the protocol chair).			

Dato: ____ / ____ 20____ Læge (underskrift): _____