A Phase 2 study for older adults with Acute Lymphoblastic Leukaemia

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To identify a safe and tolerable standard of care protocol for patients >= 60 years old with de novo Acute Lymphoblastic Leukaemia (ALL).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Observational invasive

Summary

ID

NL-OMON41230

Source
ToetsingOnline

Brief title
UKALL60+/HO117 ALL

Condition

- Leukaemias

Synonym
Acute Lymphoblastic Leukaemia (ALL)

Research involving
Human

Sponsors and support

Primary sponsor: Cancer Research UK & UCL Cancer Trials Centre
Source(s) of monetary or material Support: KWF

Intervention

Keyword: ALL, elderly

Outcome measures

Primary outcome

Complete remission rate after 2 phases of induction

Secondary outcome

* EFS at 1 year

* Treatment related mortality

* Complete remission rate after 1 phase of induction

* Prognostic significance of molecularly determined minimal residual disease (MRD) at various timepoints during therapy with respect to relapse occurrence.

* Overall Survival at 1 year

* Tolerability of treatment as determined by occurrence of key adverse effects

* Duration of in-patient hospitalisation

* Relationship between performance status/comorbidity and treatment option chosen

* Quality of life aspects assessed at diagnosis/baseline at various time points.

Study description

Background summary

Patients with ALL above 60-65 years are mostly given only palliative care because of toxicity of the regular intensive chemotherapy. Studies with intensive chemotherapy in this age group have shown poor survival rates of maximally 20 % in presumably selected patients, a recent pilot study by HOVON with an overall survival at 3 years of 50% probably being the exception. The NCRI Adult ALL Group in the UK, in collaboration with HOVON, decided to

investigate the tolerability and feasibility of a standardised therapy protocol for patients >60 years old, thereby defining a basic standard of care for future studies.

Study objective

To identify a safe and tolerable standard of care protocol for patients >= 60 years old with de novo Acute Lymphoblastic Leukaemia (ALL).

Study design

A multicentre, prospective study. The treatment will be investigated observational, the extra bone marrow aspirate is the intervention.

Study burden and risks

There may be some discomfort of the extra bone marrow punction. A bone marrow puntction is usually only a little painful and then of short period of time.
You may experience some bruising and discomfort for a few days afterwards.
Completing the quality of life questionaire will take abouth 25 minutes.
Patient will be asked to complete the list 10 times.
Treatment of patients is not different than outside this study. (treatment of ALL is heavy and has great risks. This is accountable because ALL is a life threatening diseas.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >= 60 with Acute Lymphoblastic Leukaemia (ALL) OR >= 55 with Acute Lymphoblastic Leukaemia (ALL) unsuitable for the UKALL14 or HOVON 100 trial
• Newly diagnosed, previously untreated ALL (a steroid pre-phase of 5-7 days may be given before study registration)
• Written informed consent

Exclusion criteria

• Known HIV infection
• Blast transformation of CML
• Mature B-cell leukemia i.e. Burkitt*s disease t(8,14)(q24;q32) and variant c-myc translocations e.g. t(2;8)(p12;q24),t(8;22)(q24;q11)
• Women who are pregnant or lactating

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	22-01-2016
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01616238
CCMO	NL44500.078.14