Public Title: Role of autologous bone marrow transplantation plus maintenance therapy in acute lymphoblastic leukemia in adults.

Scientific Title: Role of autologous hematopoietic stem cell transplantation plus maintenance therapy in Ph negative acute lymphoblastic leukemia (ALL) in adults.

Short Title: ALL-SCT Ph negative

Id KN/ELN: LN_CZECHL_2010_340

Trial Group: Czech Leukemia Study Group for Life (CELL)

Phase: Phase IV

Disease: Acute lymphoblastic leukemia (ALL) All subtypes

Stage of Disease: de novo/non-treated

Aim:
- Prolongation of overall survival of Ph- patients after autologous SCT + maintenance in comparison with chemotherapy or autologous SCT alone
- Tolerability of maintenance therapy after autologous SCT in ALL patients and the effect on progression free survival.

Inclusion Criteria:
- Ph negative acute lymphoblastic leukemia
- No previous treatment for ALL
- Age 18-70
- Signed informed consent
- No serious comorbidities
- No HLA identical sibling or unrelated donor or patient not suitable for allogeneic SCT

Exclusion Criteria:
- Previously treated ALL
- Performance status 3 or 4
- Non compliance of patient
- High-risk ALL patient with donor of allogeneic hematopoietic stem cells (sibling or unrelated)

Age: <= 70 years

Status: No longer recruiting

Start of Recruitment: 04.01.2010

Recruiting countries: Czech Republic

Scientific Contact (WHO): Doubek, Michael (Studienarzt, MD)
University Hospital Brno
Jihlavská 20
62500 Brno
Tel: +420 (0)532 233 642
Fax: +420 (0)532 233 603
Email: mdoubek@fnbrno.cz

Contact Person: Study Physician
Doubek, Michael
Tel: +420 (0)532 233 642
Fax: +420 (0)532 233 603
Email: mdoubek@fnbrno.cz

Centre of Trial: University Hospital Brno

Supporters: Czech Leukemia study Group for Life.
Interventions

- Treatment is started through the first and second phase of induction. The first phase of induction is composed of prednisone (p.o.; 60 mg/m²; day 1-28; tapered until day 38), vincristine (i.v.; 1.5 mg/m² [max. 2 mg]; days 1, 8, 15, 22), daunorubicin (i.v.; 45 mg/m²; days 1, 8, 15, 22), and L-asparaginase (i.v.; 10,000 U/m²; days 10, 13, 16, 19, 21, 24). The second phase of induction is composed of cyclophosphamide (i.v.; 1 g/m²; days 29 and 50), cytarabine (i.v.; 75 mg/m²; days 31-34, 38-41, and 45-48), and 6-mercaptopurine (p.o.; 30 mg/m²; days 29-50). The central nervous system prophylaxis consists of methotrexate (i.t.; 10 mg/m²; days 1, 15, 31, 45). The induction treatment is followed by 3 consolidations with high-dose methotrexate (3 g/m²; day 1) and high-dose cytarabine (4 g/m²; day 1). The last consolidation is simultaneously a mobilization regimen. It is followed by the application of filgrastim (s.c.; 10 mg/kg/day; from day 2 until HSC harvest). All transplanted patients receive conditioning regimen of total body irradiation (TBI; 12 Gy; days -6 to -4) and cyclophosphamide (60 mg/kg; day -3 and -2). Maintenance therapy with 6-mercaptopurine (p.o.; 30 mg/m²/day) and methotrexate (p.o.; 20 mg/m²/week) follows after autoHSCT for 2 years. If transplantation is not performed (patient decision, no sufficient autologous hematopoietic stem cells harvest), the patients undergo CNS irradiation (24 Gy) and subsequent conventional-dose reinduction and maintenance therapy.