MOCCCA

Chemotherapy and G-CSF for Mobilization

NCT-Nummer:
NCT03442673

Studienbeginn:
September 2018

Letztes Update:
14.01.2020

Wirkstoff:
Vinorelbine, Gemcitabine, G-CSF
Indikation (Clinical Trials):
Multiple Myeloma, Neoplasms, Plasma Cell

Geschlecht:
Alle

Altersgruppe:
Erwachsene (18+)

Phase:
Phase 2

Sponsor:
University Hospital Inselspital, Berne

Collaborator:
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Studien-Informationen

Detailed Description:

Background and Rationale High-dose chemotherapy (HDCT) with melphalan and autologous stem cell transplantation (ASCT) remains an integral component of the myeloma treatment algorithm for patients considered eligible for the procedure, nowadays performed in myeloma patients up to the age of 75 years. Until the advent of the novel agents, the initial therapy regimens commonly used were vincristine, doxorubicin, and dexamethasone (VAD) or single-agent dexamethasone, both of which shared the advantage of having little impact on stem cell mobilization and collection. Previous studies had shown that alkylating agents can potentially

affect the stem cell pool and thus interfere with the ability to collect adequate numbers of stem cells. However, VAD is no longer uses nowadays, whereas current lenalidomide-containing combinations significantly affect stem cell collection. .In Switzerland, the combination of non-myeloablative chemotherapy with vinorelbine or gemcitabine and G-CSF is the current standard procedure. With the predominant use of bortezomib during induction treatment more patients have pre-existing neurotoxicity. Vinorelbine can aggravate this problem. Recently data have shown that a mobilization with gemcitabine together with G-CSF is safe and effective in myeloma patients. Whether chemotherapy is mandatory at all to achieve the same reliable and cost-effective mobilization is currently unknown. The investigators therefore consider that a direct comparison between vinorelbine/gemcitabine and G-CSF versus G-CSF alone is justified.

Objective:

The primary objective is to show non-inferiority of cytokine stimulation with G-CSF compared to chemotherapy stimulation with vinorelbine (or gemcitabine) together with G-CSF for the mobilization of autologous stem cells in myeloma patients in first remission.

Study Duration:

The anticipated total study duration is 42 months.

Ein-/Ausschlusskriterien

Inclusion Criteria:

- Myeloma or amyloidosis patients after standard first-line induction treatment. (Additional induction regimens in refractory myeloma patients are allowed)

- Patients must be considered being clinically fit for subsequent consolidation with high-dose melphalan-based chemotherapy with autologous stem cell support.

- Patients must be aged ≥18 years.

- Female patients of child-bearing potential must have a negative pregnancy test (urine or serum) within 14 days prior to study treatment mobilisation, and they must implement adequate measures (hormonal treatment p.o. or i.m., intra uterine surgical devices, or latex condoms) to avoid pregnancy during study treatment and for additional 12 months.

- Patients must have given voluntary written informed consent

Exclusion Criteria:

- Patients with concurrent other malignant disease can be included, but previous treatment for other malignancies must have been terminated at least 2 months before registration. Endocrine treatment (such as for breast cancer) is allowed.

- Pregnancy or lactating female patients.

- The use of any anti-cancer investigational agents within 14 days prior to the expected start of trial treatment.

Studien-Rationale

Primary outcome:

1. Number of patients achieving a sufficient number of stem cells (Time Frame - 8 days):
Number of patients achieving a sufficient number (at least 5.0 Mio/kg) of stem cells at the planned day in a single day procedure without the use of the rescue compound plerixafor

Secondary outcome:

1. Adverse events (Time Frame - 30 days after ASCT):
Number of patients experiencing toxicities/adverse events assessed according to the CTCAE 5.0 during the study period

2. Quality of life (Time Frame - 8 days):
Assessment of quality of life before and after mobilization. The EORTC Q30 questionnaire will be given to patients at screening and after mobilization

3. Pain (Time Frame - 8 days):
Assessment of pain associated with the mobilization procedure. Pain is measured with visual analogue scale before and after mobilization

4. Use of plerixafor (Time Frame - 8 days):
Number of patients requiring plerixafor for mobilization

Studien-Arme

- Active Comparator: CG (Chemotherapy/G-CSF) - Regime
  Vinorelbine 35 mg/m2 at day 1 as an i.v. infusion over 10 minutes or gemcitabine 1250 mg/m2 as a 30 minutes infusion at day 1. G-CSF will be started at day 4 at 10mcg/kg b.w. split in two daily doses, until the end of the stem cell collection procedure, with the first collection attempt on day 8.
- Experimental: G (G-CSF) - Regime
  G-CSF at 10mcg/kg b.w. split in two daily doses starting from day 1 until the end of the stem cell collection procedure, with the first collection attempt on day 5.

Geprüfte Regime

- Vinorelbine:
  Stimulation with vinorelbine together with G-CSF for mobilization of autologous stem cells
- Gemcitabine:
  Stimulation with gemcitabine together with G-CSF for mobilization of autologous stem cells

- G-CSF:
  Cytokine stimulation with G-CSF for mobilization of autologous stem cells

Studienleiter

Barbara Jeker, MD
Study Chair
Department for Medical Oncology University Hospital/Inselspital 3010 Bern Switzerland

Kontakt

Barbara Jeker, MD
Kontakt:
Phone: +41 31 632 41 95
E-Mail: barbara.jeker@insel.ch

Thomas Pabst, MD
Kontakt:
Phone: +41 31 632 84 30
E-Mail: thomas.pabst@insel.ch

Studienlocations (1 von 1)

Department for Medical Oncology University Hospital/Inselspital
3010 Berne
Switzerland

Status: Rekrutierend