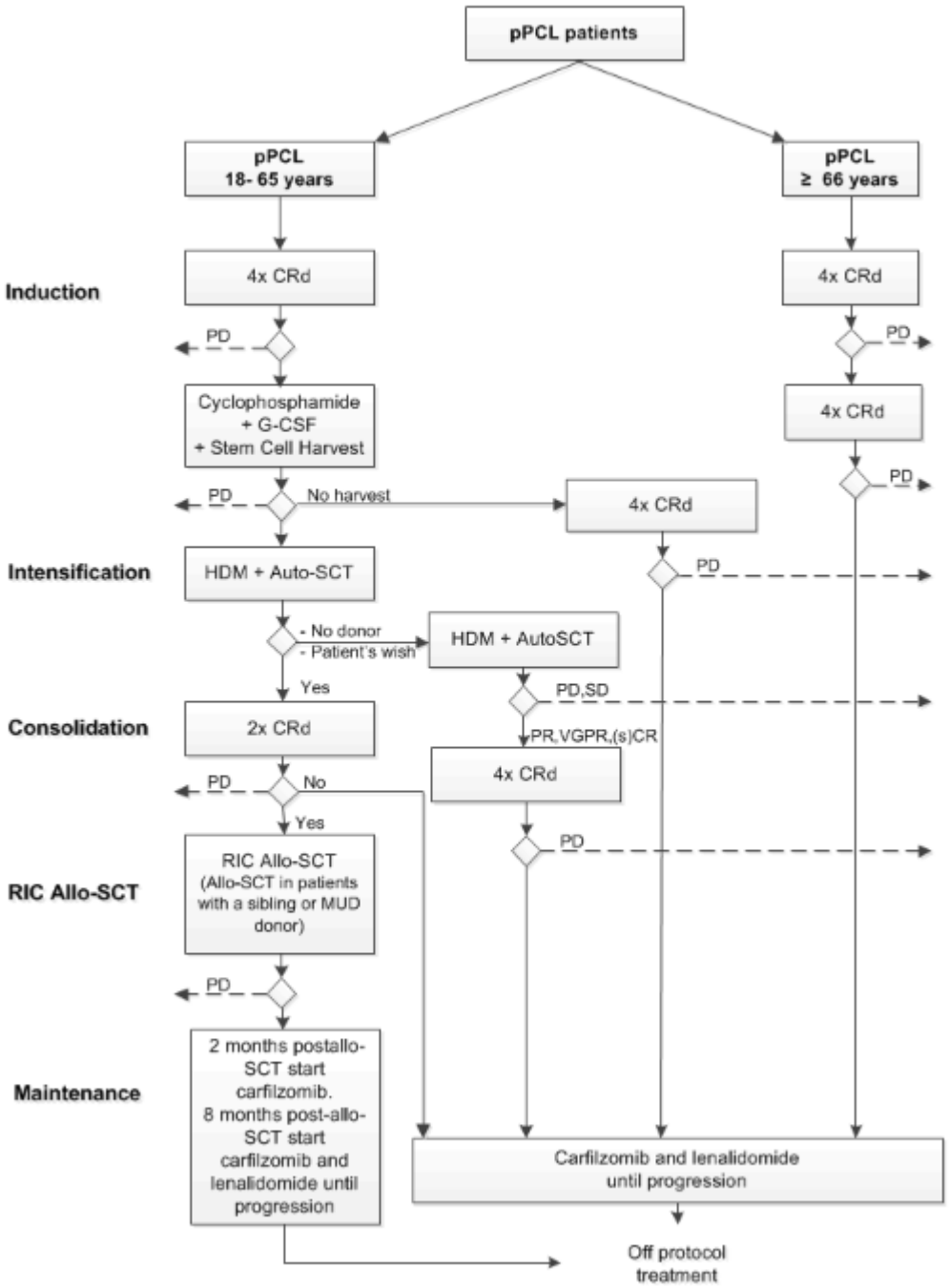
SAMENVATTING HOVON 129

TITEL
Carfilzomib and Lenalidomide-based treatment for younger and eldery newly diagnosed primary plasma cell leukemia patients

DOEL
To evaluate progression-free survival in adult pPCL patient by incorporation of carfilzomib and lenalidomide in induction, consolidation and maintenance therapy

POPULATIE
Patients with symptomatic pPCL, previously untreated, ISS stages I-III, age ≥18 years

Scheme of study



INCLUSIE CRITERIA

- Patients with diagnosis of symptomatic pPCL (see appendix A)
- Measurable disease as defined by the presence of M-protein in serum or urine (serum M-protein > 10 g/l or urine M-protein > 200 mg/24 hours or abnormal FLC ratio with involved free light chain (FLC) > 100 mg/l) or proven plasmacytoma by biopsy)
- Age ≥18 years
- WHO-performance status 0-3 (but WHO=3 is allowed only when caused by pPCL and not by co-morbid conditions)
- Written informed consent
- Patient capable of giving informed consent (patient is legally, physically and mentally capable of giving consent)
- All men and women of childbearing potential should use adequate contraception during the study. Sperm could be frozen from men with child wish before start of treatment
- Negative pregnancy test at entry (if applicable)
- Patient is willing and able to adhere to the requirements of the lenalidomide Pregnancy Prevention Program (PPP)

EXCLUSIE CRITERIA

- Any current CNS involvement with disease refractory to intrathecal chemotherapy.
- Female patients who are pregnant or breast feeding.
- HIV positive patients
- Active malignancy other than pPCL requiring treatment, or a malignancy that has been treated with chemotherapy currently affecting bone marrow capacity
- Patients with active, uncontrolled infections
- Severe neurological or psychiatric disease
- Severe cardiac dysfunction (NYHA classification II-IV, see appendix E) - Myocardial infarction within 6 months, unstable angina, and cardiac arrhythmias which are not controlled by conventional treatment (including medications and cardiac devices)
- Severe pulmonary dysfunction
- Significant hepatic dysfunction (serum bilirubin or transaminases ≥ 3.0 times normal level), unless related to pPCL
- Patients with GFR < 15 ml/min
- Known history of allergy to Capsidol (a cyclodextrin derivative used to solubilize carfilzomib)
- Hypersensitivity to the active substances or to any of the excipients of the drug products
- Previous chemotherapy or radiotherapy except local radiotherapy in case of local myeloma progression or corticosteroids maximum 7 days for symptom control or stabilization(this includes dexamethasone 40 mg daily) or inthrathecal chemotherapy in case of CNS involvement
- Systemic AL amyloidosis
- Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule