Paclitaxel 80, Breast Cancer, adjuvant

Protocol-ID: 581 V1.2 (Complete), PACL80, Breast Ca, adj.

Indication(s)

- Breast Cancer; ICD-10 C50.-

Protocol classification

- Classification: alternative
- Intensity: Standard dose
- Therapy phase:
- Therapy intention: curative

Cycles

Cycle length 7 days, recommended cycles: 12

Protocol sequences

- EC (EPIR90/CYCL600), Breast Ca, adj. (PID579) -|- PACL80, Breast Ca, adj. (PID581)

Risks

- Emetogenicity (MASCC/ESMO): low (10-30%)
- Neutropenia: low (<10%) °3-4: 2%
- Febrile Neutropenia: low (<10%) °3-4: 1%
- Infections: CTC AE °3-4: 3%
- Fatigue: CTC AE °3-4: 3%
- Neuropathy: CTC AE °2-4: 27%
- Myalgias: CTC AE °3-4: 2%

Therapy

Hydration: Balanced Crystalloid Solution **HYD**

Access: peripheral venous

Hydration before, during, or after antitumor therapy

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	**Balanced Crystalloid Solution**	500 ml		i.v.	30 min	30 min before Paclitaxel (d1)

Allergy prophylaxis: Paclitaxel Allergy Prophylaxis **AP**

Access: peripheral venous

Dexamethasone, dimetinden maleate, cimetidine

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	**Dexamethasone**	20 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Paclitaxel (d1)
1	**Dimetinden**	4 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Paclitaxel (d1)
1	**Cimetidine**	300 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Paclitaxel (d1)

Medical tumor therapy: Paclitaxel 80 mg/m² **CTX**

Access: peripheral venous

weekly therapy

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	**Paclitaxel**	80 mg/m² BSA	NaCl 0.9% 250 ml	i.v.	60 min	Sequence

Concomitant therapy supplements

Dexamethasone for antiemesis is covered by dexamethasone of allergy prophylaxis.

Notes

Paclitaxel administration over 60 minutes is only up to a dose of 100 mg/m².

Cycle diagram

Hydration: Balanced Crystalloid Solution

	Week 1 / d						
Substance	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Balanced Crystalloid Solution (i.v.)							

Allergy prophylaxis: Paclitaxel Allergy Prophylaxis

	Week 1 / d						
Substance	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Dexamethasone (i.v.)							
Dimetinden (i.v.)							
Cimetidine (i.v.)							

Medical tumor therapy: Paclitaxel 80 mg/m²

	Week 1 / d						
Substance	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Paclitaxel (i.v.)							

Cycles

Cycle length 7 days, recommended cycles: 12

Controls:

- Blood count: on day 1 and subsequently weekly
- ECG Risk of developing conduction disorder during paclitaxel therapy, regular ECG monitoring.
- Day 1: GOT, GPT, GGT, Bilirubin, AP, Cholinesterase Liver value monitoring before and during paclitaxel therapy.
- Day 1: Na^+, K^+, Ca^{2+}, Mg^{2+}

Pharmacokinetics

Paclitaxel: hepatischer Abbau, biliäre Elimination 25%, renal < 10%
Cimetidin: CYP450 Inhibitor, vielschichtige Interaktionen möglich

Original indication

Paclitaxel weekly, Breast Cancer, adjuvant

Original author

Sparano JA (2008)

Origin

Eastern Cooperative Oncology Group, Philadelphia, US

References

- Sparano JA, Weekly paclitaxel in the adjuvant treatment of breast cancer., N Engl J Med 2008 Apr 17;358(16):1663-71 [PMID]
- De Laurentiis M, Taxane-based combinations as adjuvant chemotherapy of early breast cancer: a meta-analysis of randomized trials., J Clin Oncol 2008 Jan 1;26(1):44-53 [PMID]

Recommendations

- 08/2019: European Society for Medical Oncology
- 03/2023: National Comprehensive Cancer Network

Links

- One-hour paclitaxel infusions: review of safety and efficacy. [PMID]

Status

Valid since 2023-09-16, Version 1.2, last updated 2023-09-16

Last modification: V1.2: Protocol name changed according to current standard V1.1: Cato test done. Revision of allergy prophylaxis according to summary of product characteristics, change of H2- antagonist for Paclitaxel from Ranitidine to Cimetidine according to DGHO recommendations 10/2019. V1.0: Cato test again due to correct cycle count and diagnoses. V0.1: Cato test successful. Application of this protocol after 4 cycles of EC, see EC x 4 followed by Pacl, Breast Ca, adjuvant, A. Duration according to primary literature. This protocol was established based on AGO and NCCN recommendation allowing extrapolation from AC+Paclitaxel to EC+Paclitaxel and recommending use in dose equivalent due to more favorable side effect profile.

Important notice