modified FOLFOX-6 - Oxaliplatin 85 / Folinic Acid 400 / Fluorouracil 2400, colon carcinoma adjuvant

Protocol-ID: 644 V1.1 (Complete), mFOLFOX-6 (OXAL85/CFOL400/FU2400), Colon Ca, adj.

Indication(s)

- Colon Cancer; ICD-10 C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C19

Protocol classification

- Classification: current standard
- Intensity: Standard dose
- Therapy phase:
- Therapy intention: curative

Cycles

Cycle length 14 days, recommended cycles: 12

Risks

- Emetogenicity (MASCC/ESMO): moderate (30-90%)
- Neutropenia: high (21-40%)
- Febrile Neutropenia: low (<10%)
- Thrombocytopenia below 50 000/µl: low (<10%) °3-4: 3.4%
- Diarrhea: CTC AE °3-4: 9.7%
- Fatigue: CTC AE °3-4: 7.2%
- Thromboembolic Event: CTC AE °3-4: 4.6%
- Neuropathy: CTC AE °3-4: 14.4%, sensory
- Dehydration: CTC AE °3-4: 4.0%
- Allergic Reaction: CTC AE °3-4: 4.7%
- Pain: CTC AE °3-4: 6.3%

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.	60 min	60 min before Oxaliplatin (d1)

Antiemesis: Emetogenicity moderate, GRAN i.v., DEXA i.v. **AE**

Access: peripheral venous

ASCO 2015, DGHO 2016, DKG 2016, MASCC/ESMO 2016, if palonosetron not available

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	**Dexamethasone**	8 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Oxaliplatin (d1)
1	**Granisetron**	1 mg	NaCl 0.9% 50 ml	i.v.	5 min	15 min before Oxaliplatin (d1)
or other 5-HT3 receptor antagonist						
2-3	**Dexamethasone**	8 mg		p.o.		1-0-0-0

Antineoplastic therapy: mFOLFOX6 **ANTX**

Access: central venous, port

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	**Oxaliplatin**	85 mg/m² BSA	Dextrose 5% 500 ml	i.v.	2 h	Sequence
1	**Folinic acid**	400 mg/m² BSA	NaCl 0.9% 250 ml	i.v.	2 h	Sequence
1	**Fluorouracil**	400 mg/m² BSA	none	i.v.	1 min	Sequence
Bolus application						
1	**Fluorouracil**	2400 mg/m² BSA	NaCl 0.9% 500 ml	i.v.	46 h	Sequence

The volume of the carrier solution refers to inpatient therapy with infusion pumps. When using syringe pumps or ambulatory systems, a different volume (e.g. 100 ml) can be used.

Substance links

Links to substances are found here.

Notes

Oxaliplatin is administered before folinic acid for pharmacological reasons.

Cycle diagram

Hydration: Balanced Crystalloid Solution

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

Antiemesis: Emetogenicity moderate, GRAN i.v., DEXA i.v.

	Week 1 / d						
Substance	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Dexamethasone (i.v.)							
Granisetron (i.v.)							
Dexamethasone (p.o.)							

Antineoplastic therapy: mFOLFOX6

	Week 1 / d						
Substance	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Oxaliplatin (i.v.)							
Folinic acid (i.v.)							
Fluorouracil (i.v.)							
Fluorouracil (i.v.)							

Cycles

Cycle length 14 days, recommended cycles: 12

Controls:

- Blood count: on day 1 and subsequently weekly
- DPD Exclude deficiency: Uracil levels or DPD gene mutations.
- Day 1: GOT, GPT, GGT, Bilirubin, AP, Cholinesterase Fluorouracil: dose reduction is necessary in the presence of concomitant impaired hepatic and renal function.
- Day 1: Creatinine, glomerular filtration rate (GFR) Oxaliplatin

Pharmacokinetics

Fluorouracil: 90% metabolische Elimination, 10% renal
Oxaliplatin: renale Elimination der Metabolite

Original indication

adjuvant treatment of colon carcinoma, stage 2/3, ECOG 0-1

Original author

Allegra CJ (2009)

Origin

University of Florida, Division of Hematology and Oncology, Gainsville, Florida, NSABP

References

- Allegra CJ, Initial safety report of NSABP C-08: A randomized phase III study of modified FOLFOX6 with or without bevacizumab for the adjuvant treatment of patients with stage II or III colon cancer. J Clin Oncol 2009 Jul 10;27(20):3385-90. doi: 10.1200/JCO.2009.21.9220. PMID: 19414665. [PMID]
- Allegra CJ, Phase III trial assessing bevacizumab in stages II and III carcinoma of the colon: results of NSABP protocol C-08. J Clin Oncol 2011 Jan 01;29(1):11-6. doi: 10.1200/JCO.2010.30.0855. PMID: 20940184. [PMID]

Recommendations

- 07/2020: European Society for Medical Oncology
- 11/2023: National Comprehensive Cancer Network

Status

Valid since 2024-01-04, Version 1.1, last updated 2024-10-27

Last modification: V1.1: Title correction V1.0: Cato test done with cycle count and ICD-10 codes. Dexamethasone for prophylaxis of delayed emesis analogous to the guidelines on day 4 deleted. V0.1: Durations according to primary literature, sequence Oxaliplatin before Fluorouracil according to summary of product characteristics.

Important notice