

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

Protocol-ID: 644 V1.1 (Standard), 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								
Acce	ccess: peripheral venous							
Hydration before, during, or after antitumor therapy								
Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure		

ΑE

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

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

Antin	Antineoplastic therapy: mFOLFOX6								
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/m ² 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.

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

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: <u>European Society for Medical Oncology</u>
- 11/2023: National Comprehensive Cancer Network

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