

# 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%</li>

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**

Hydr	Hydration: Balanced Crystalloid Solution  Access: peripheral yappays										
Acce	ss: peripheral venous										
Hydra	ation 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 oth	er 5-HT3 receptor antagonist					
2-3	Dexamethasone	8 mg		p.o.		1-0-0-0

Antineoplastic therapy: mFOLFOX6								
Acces	ss: 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.

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