

Radical excision T1-2 N0 M0 rectum carcinoma

Local investigator  
Informed consent + registration patient  
ALEA: pathology number, year of birth, centre

Central histopathology review

Randomisation

Registration  
Watchful waiting

Adjuvant  
Chemoradiation  
(within 4-12 weeks)

TME  
Surgery  
(within 4-12 weeks)

Strict  
follow-up

Normal  
follow-up

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## INCLUSION CRITERIA

1. Radical local excision (TEM/TAMIS/EMR/ESD/polypectomy)
2. High-risk pT1 or low-risk pT2 tumor
3. T1-2N0M0 (MRI pelvis, CT-abdomen, CT/X-ray chest)
4. Fit to undergo surgery (WHO 0-2)

## EXCLUSION CRITERIA

1. Irradical excision (tumor in resection plane), re-excision allowed
2. pT1 < 3cm without risk factors, pT1 > 5 cm or pT2 > 3cm
3. Recurrent or simultaneous colorectal cancer
4. Previous pelvic radiotherapy
5. Concomitant malignancies (disease-free for 5 years)

Tumor Stage	Differentiation		Invasion		Size		Sm3 / Haggitt 4	Budding / clustering
	Well-to-moderate	Poor	Lymphatic	Venous	> 3cm	> 5cm		
pT1								
pT2								

Months	Follow-up schedule									
	3	6	9	12	18	24	36	48	60	
Outpatient clinic	★	X	★	X	X	X	X	X	X	
CEA		X		X	X	X	X	X	X	
Sigmoidoscopy		★				★	★			
Colonoscopy				X				X		
MRI		★			★	X	★		★	
CT/X-ray chest & CT/US-abdomen		X		X	X	X	X	X	X	
Questionnaires	X	X		X		X	X			

X = Follow-up both groups (MRI after 24 months in both groups)

★ = Additional follow-up for intervention group (chemoradiotherapy)



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