Organ preservation in rectal cancer:

STARTREC

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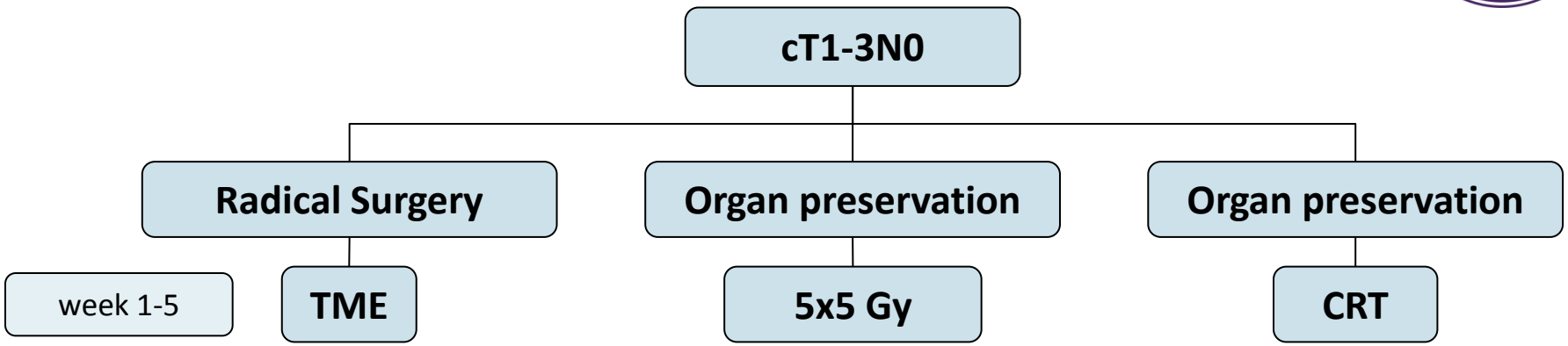
Radboudumc

STARTREC – Study design

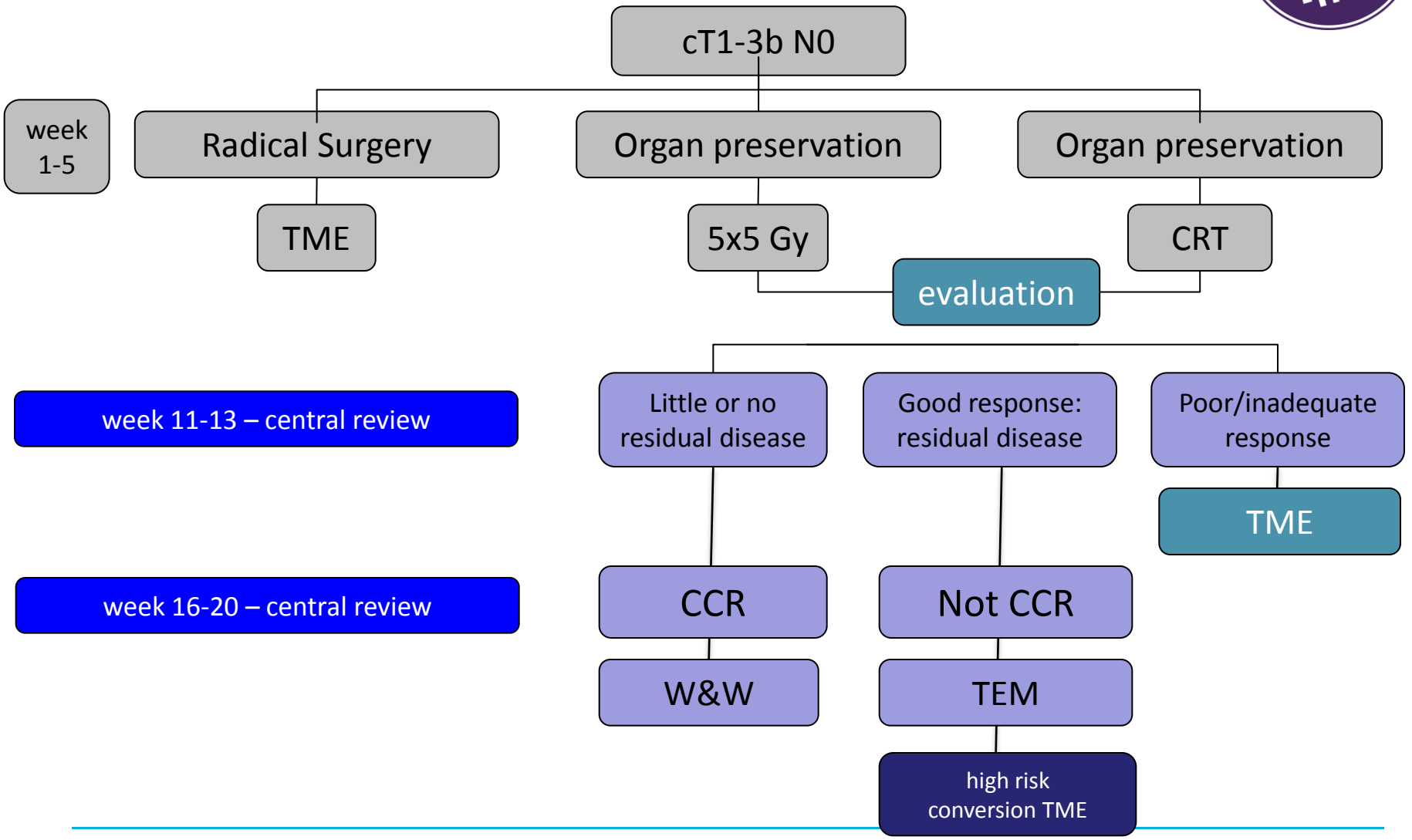


Inclusion criteria

- Biopsy proven adenocarcinoma of the rectum
- mriT1-3bN0 (with ≤5mm of mesorectal invasion) rectal tumour
- MDT determines that all of the treatment options are feasible
- Aged 18 or over
- Creatinine clearance, neutrophils, transaminase, bilirubin
- ECOG performance status 0-1

Exclusion criteria

- Evidence of metastatic disease
- MRI: Node positive, EMVI, mucinous tumour, MRF≤ 1 mm
- Maximum tumour diameter > 40mm
- Tumour position anterior, above the peritoneal reflection on MRI
- No residual luminal tumour following endoscopic resection
- Contraindications to radiotherapy, chemotherapy
- Pregnant, lactating or women not using adequate contraception
- Unable or unwilling to provide written informed consent


cT1-3b N0
week 1-5
Radical Surgery
Organ preservation
Organ preservation
TME
5x5 Gy
CRT
evaluation
week 11-13 – central review
Little or no residual disease
Good response: residual disease
Poor/inadequate response
TME
week 16-20 – central review
CCR
Not CCR
W&W
TEM
high risk conversion TME

Minimal follow-up schedule (after organpreservation)

				MONTHS AFTER start of (Chemo) RADIATION THERAPY [a]							
	Prior to patient entry	Prior to (chemo) Rtx	After (chemo) Rtx	3	4.5	6	9	12	18	24	36
Informed Consent	X										
Histopathology	X										
(chemo) Rtx delivery & toxicity			X								
Clinical evaluations		X	X	X	X	X	X	X	X	X	X
Quality of Life [b]		X						X		X	
Colonoscopy	X							X			
DRE, endoscopy +/- ERUS		X		X	X	X	X		X	X	X
High resolution MRI pelvis [c]	X			X		X	X	X	X	X	X
CT scan Thorax-abdomen	X							X		X	X

End points for phase II feasibility

PRIMARY

- Target international recruitment
  - >=4 patients per month in year 1 Netherlands UK Denmark
  - >=6 patients per month in year 2 (total of 120 patients)

Ultimate goal is Phase III trial with pelvic failure as primary endpoint

STARTREC

RadboudUMC
VUMC/AMC
AvL/Slootervaart
Ijsselland/ErasmusMC
Laurentius/MUMC
LeeuwardenMC
CatherinaZH
Amphia
Diakonessen/UMCU
LUMC
TEZ
Isala

Radboudumc

STARTREC

- 12 centra in the Netherlands for phase II trial
- 1 july started in Nijmegen and Zwolle
- First patient included
- Eindhoven and Maastricht/Roermond soon to start
- Rest of the Netherlands this summer

Thank you

- **Prof. Dr. Hans de Wilt**
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- Nijmegen
- The Netherlands
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