



STAR-TREC

Can we Save the rectum by watchful waiting or TransAnal microsurgery following (chemo)Radiotherapy versus Total mesorectal excision for early Rectal Cancer?

Sell Your Study





- ***Design:***

Multicentre, international randomised, phase II feasibility study

- ***Aim:***

Demonstrate sufficient international recruitment in a study comparing organ saving approaches vs standard TME surgery in rectal cancer

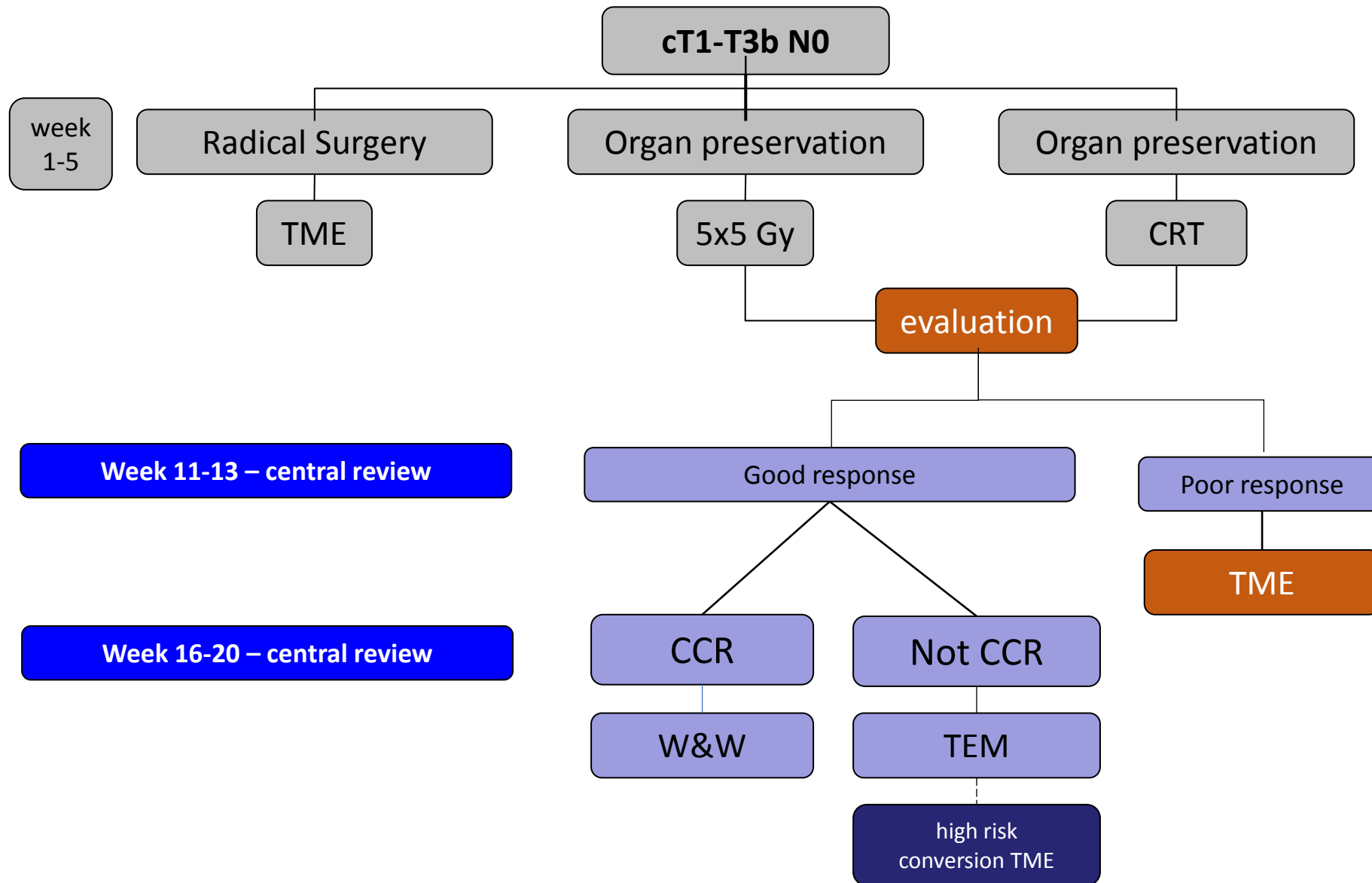
- ***Patients:***

Biopsy proven T1-3bN0M0 <4cm adenocarcinoma rectum

All treatment options feasible

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- **Primary endpoint:**

Target international recruitment

>=4 patients per month in year 1 **internationally**

>=6 patients per month in year 2 (total of 120 patients)

- **Main secondary endpoints:**

- Is the organ saving rate >50% at 12 months in the experimental arms?

- Safety (morbidity, mortality, local failure etc)

- Efficacy (% stoma, conversion rates, QOL, overall survival etc)

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• *Participating centers:*



- **Queen Elizabeth Hospital, Birmingham**
- **Good Hope Hospital, Birmingham**
- Bradford Royal Infirmary, Bradford
- St James University Hospital, Leeds
- York Hospital, York
- Manchester Royal Infirmary, Manchester
- Christie Hospital, Manchester
- Churchill Hospital ,Oxford
- Freeman Hospital, Newcastle-upon-Tyne
- Colcehster General Hospital, Colchester
- Univesity Hospital Wales, Cardiff
- Norfolk and Norwich University Hospital, Norwich
- Queen Elizabeth Hospital, Gateshead
- Ninewells Hospital, Dundee
- Addenbrookes Hospital, Cambridge



- Odense University Hospital, Odense
- Aarhus University Hospital, Aarhus
- Zealand University Hospital, Roskilde/Køge
- Aalborg University Hospital, Aalborg
- Hvidovre Hospital , Hvidovre



- **Radboudumc, Nijmegen**
- **Leiden UMC, Leiden**
- **NKI / AMC, Amsterdam**
- VUMC, Amsterdam
- **Catharina hospital, Eindhoven**
- **Laurentius hospital, Roermond**
- **Isala hospital, Zwolle**
- Ijsselland hospital, Capelle aan de IJssel
- **Diakonessenhuis, Utrecht**
- Amphia hospital, Breda
- Elisabeth-Twee Steden hospital, Tilburg
- Medical Center Leeuwarden, Leeuwarden



9 / 32 centres now open for inclusion

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- ***Number pts needed:***
120 internationally
- ***Number pts included:***
11 in total, of which 5 in the UK and 6 in the NL
- ***What's next?***
Opening of remaining sites, including Denmark

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