Study synopsis

Protocol title:	Separation surgery followed by Stereotactic Ablative Body Radiotherapy versus Stereotactic Ablative Body Radiotherapy alone for spinal metastases invading the spinal canal: a randomised, non-inferiority trial
Alias:	SABR-MESCC
Protocol number:	CTO21003GZA
Primary registry and trial identifying number:	Clinicaltrials.gov
Date of registration in primary registry:	
Secondary identifying numbers:	BUN
Funding:	Research project funded by Kom op tegen Kanker (Stand up to Cancer), the Flemish cancer society from 2021 to 2025
Sponsor:	GZA vzw Oosterveldlaan 22, 2610 Wilrijk, Belgium
Study responsible physician:	Dr. Charlotte Billiet
Investigator(s)/study center(s):	Dr. Charlotte Billiet, GZA hospital Wilrijk Dr. Samual Bral, OLVZ Aalst Dr. Katleen Verboven, Jessa Ziekenhuis Dr. Erik Van de Kelft, AZ Nikolaas Dr. Marika Rasschaert, UZA Dr. Julie van der Veen, AZ Sint-Maarten Dr. Isabelle Kindts, AZ Groeninge Dr. Charlotte Billiet, ZNA Dr. Charlotte Billiet, AZ Klina Dr. Evelyn Van de Werf, ZOL
Medical condition or disease under investigation:	Patients with malignant epidural spinal cord compression (MESCC), Bilsky grade 1c, 2 and 3 who are ambulatory with or without aid (rollator, cane, one persons help)
Intervention:	Control arm: separation surgery followed by SABR Study arm: SABR
Key inclusion and exclusion criteria:	Each potential subject must satisfy all of the following criteria to be enrolled in the study: 1. Diagnosis of a solid malignant tumour (preferentially histologically proven;alternatively obtained by spinal surgical procedure) 2. Age 18 years or older

	3. Histological, radiological or scintigraphical evidence of spinal metastasis (no limitation in the number of sites of metastases) 4. Spinal instability neoplastic score (SINS) <13 (i.e. no need for stabilisation of the spine) 5. Spinal metastasis with MESCC: Bilsky grade 1c, 2 and 3. 6. Ambulatory: being able to walk 10m without aid or with aid (cane, rollator, one persons help). Frankel grade E or D. 7. Life expectancy estimated to be at least 3 months. 8. World Health Organization (WHO) Performance Status of 0-2 9. Patient has given written informed consent. Each potential subject must NOT satisfy any of the following criteria to be enrolled in the study: 1. Contra indication for MRI scan (e.g. pacemaker) 2. Previous RT or surgery at the level of the affected vertebrae 3. Non-solid primary tumours (e.g. lymphoma, multiple myeloma, germ cell tumours) 4. Non ambulatory at presentation 5. More than 3 affected vertebrae in one target site 6. More than 2 treatment sites 7. SINS ≥ 13 (unstable spine)
Study design:	Randomised controlled trial
Date of first enrolment:	
Target sample size:	128
Recruitment status:	Not yet recruiting
Primary outcome(s):	Ambulatory function 3 months post treatment defined as: 1. Able to walk 10m without aid 2. Able to walk 10m with aid (rollator, cane, one person) 3. Not able to walk
Key secondary outcome(s):	1. Local control: - based on imaging according to the international SPine response assessment In Neuro-Oncology (SPINO) group report (*Thibault et al*): MRI 3-monthly after treatment. - Classified towards 'In-field' local recurrence (LR) (if >90% of recurrent volume was within the planning volume) versus 'out of field' (if <20% of recurrent volume was within treated volume) versus 'marginal' (if 20-90% of recurrent volume was within treated volume) *(Bishop et al).* 2. Time to loss of ambulation 3. PFS: time of study registration to local recurrence (LR) 4. Overall survival 5. Time to reintervention, type of reintervention 6. Acute and late toxicity measured with CTCAE version 5.0 7. QoL according to the EORTC QLQ-C15 and BM22 questionnaires 8. Pain response