

Standard Operating Procedure

Blood Sampling and cardiac parameters WP2 Task 2.3 Cardiovascular toxicities, HARMONIC

Version: 1.0

Date of validity: (First patient inclusion)

Valid until: (Last patient inclusion)

Compiled by:	Approved by:	Accepted by:
Date:	Date:	Date:
Signature:	Signature:	Signature:

Abbreviation

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1. Objectives

The purpose of this Standard Operating Procedure (SOP) related to cardiovascular task (Task2.3) is to ensure the procedure of imaging and biological biomarkers for patients included in this task.

1. Contact related to this SOP

If there is any question or information needed, please contact:

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2. Applicable documents

- WP2 Study Protocol, Version xxx

3. Responsibilities/Partners

Partners	Clinicians & Epidemiologists
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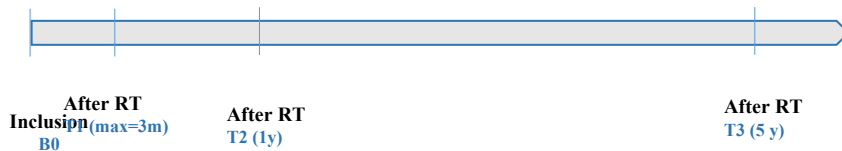
4 Inclusion criteria

- Patients treated for solid tumor (included central nervous system tumor) or lymphoma
- Diagnosed at an age <22 years-old
- Treated with external beam radiation therapy (EBMRT) as part of their oncological treatment
- With one or more of following EBRT fields:

- (1) Mediastinal irradiation
- (2) Bipulmonary irradiation
- (3) Chest radiation (including vertebral and paravertebral radiation) with at least one part of the heart in, or at the edge of, radiation field
- (4) Craniospinal radiation
- (5) Abdominal radiation with at least one part of the heart in, or at the edge of, radiation field

- Informed consent of parent/guardian for patients aged <18years at inclusion
- Informed consent of patient if aged ≥18years at inclusion

5. Time Frame of Collection



Time points	
B0	Before RT
T1	After radiotherapy up to 3 months
T2	1 year after radiotherapy
T3	5 years after radiotherapy
Optional	10 years after radiotherapy and then every 5 years

4. Performance

4.1 Imaging parameters

4.1.1 Time Frame of Collection

	B0	T1 M3	T2 M12	T3 M60	Optional M120
Cardiac Echography	X	X	X	X	X
Ejection Fraction, mode Simpson Biplan					
Ejection Fraction, mode Teicholz					
Shortness fraction					
Cardiac frequency					
Diastolic function (mitral E/A ratio)					
Left ventricular size (end-diastolic dimension z-scores)					
Pulmonary artery systolic pressure					

*M: months number

4.1.2 Requirements

Echocardiogram

4.1.3 Potential risks

No risk identified

4.1.3 Purpose

Early changes in imaging markers of cardiovascular damages (cardiac echography)
 o ejection and shortness fraction
 o others (e.g. cardiac frequency, mitral E/A ratio, end-diastolic dimension z-scores)

4.2 Biological parameters

4.2.1 Time Frame of Collection

Specific blood sampling for WP2.3 markers (EDTA tube). Markers measured at centers	B0	T1 M3	T2 M12	T3 M60	Optional M120
NT-proBNP	X	X	X	X	X
Troponine	X	X	X	X	X
CPK	X	X	X	X	X
Total cholesterol, HDL, LDL	X	X	X	X	X
Triglycerides	X	X	X	X	X
Glycosylated haemoglobin (HbA1c)	X	X	X	X	X
Hemoglobin	X	X	X	X	X
Creatinine	X	X	X	X	X
Ferritin	X	X	X	X	X

4.2.2 Requirements

Amount	Equipment
1	Roller stool (for the examiner)
1	Hospital bed or blood collection chair with armrest (for the subject)
1	Armrest (washable)
1	Special waste container / Sharps disposal box (1 in use, 1 replacement)
1	Infectious waste biohazard bins
1	Tourniquet
2	Test tube rack (for the filled blood collection tubes)
1	Vomit bowl (for single use)
1	Radio controlled clock
	Special Supply
2	Winged blood collection set (butterfly devices) (different sizes)
1	Antiseptic skin disinfection spray before blood sampling
1	Surface disinfection (devices, arm rests, work surfaces)
1	Cellulose swabs with dispenser
2	Plaster
1	Pack of non-sterile gloves (different sizes)
1	Package garbage bags
1	Pack of tissues

Kommenterede [HN1]: Les mêmes que le task 2.2
 Endocrino
 Il va falloir faire le tri

	Subject specific label set from the respective hospital/laboratory XY (adapt to local conditions!)
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Contacts

Project Coordination and Management

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