

The E3-3036 IAEA study on TACE versus SBRT for hepatocellular carcinoma

Thank you for your contributions to the investigator meeting in Aarhus 16-18 April 2018. The protocol is now open in a number of centers and we urge you to start including your patients in the study.

During the meeting, we decided to do the following changes of the protocol:

- Follow-up at 3 months was postponed to 4 month (Three TACE sessions are allowed. Thus, the first follow-up scan for TACE-patients can be at 4 months. This should be similar for the SBRT-patients. The 4 months follow-up is the first time-point where a progression can be declared.
- It is allowed in the SBRT-arm to perform a CT-scan for follow-up at 2-3 months, but a failure will be dated at the 4-month follow-up.
- Base-line assessment of the Child-Pugh score should be within 6 weeks and lab tests should be within 2 weeks from randomization/inclusion.
- When conventional TACE with Lipiodol is used, the abdominal CT may be supplemented by MRI of the liver.
- Following the meeting, Dr Nitin Shetty (Tate Memorial) has revised the description of the DEB-TACE and c-TACE procedures.

In addition, a questionnaire for assessment of the quality of the TACE procedures – similar to the one on the SBRT - has been designed by Dr Nitin Shetty. It will be circulated to the interventional radiologists participating in the trial.

A revised version of the protocol is attached to the newsletter.

User/password for www.SBRT.dk

Your Username is the e-mail address that you have registered to the IAEA. **If you have not already registered, you will receive a personal mail where you will be requested to create your password. Please respond instantly to this mail.** Additional personal from your center (radiation oncologist/interventional radiologist/ research nurse) may register as well at the www.sbrt.dk.

eCRF

Once the patients has been successfully randomized, the ON-STUDY eCRF should be completed. When the patient has received his treatment, the SBRT/TACE eCRF should be done. Similarly FOLLOW-UP forms etc. should be done during follow-up. They can all be found on the www.SBRT.dk. You will only have access to your own patients.

Status of the participating centers:

	Dummy run	TACE QA	Reference dosimetry	IROC	PRC	User/password for www.sbrt.dk	Start	# pts per year
NCI, Cairo	Yes	31/5 18	Yes	YES	YES	YES	Feb 18	20
Delhi	Yes	31/5 18	Yes	?	Yes	YES	Apr 18	12

Tata Memorial Mumbai	Yes	31/5 18	Yes	?	Yes	-	Apr 18	6
Shanghai	Yes	31/5 18	- (31/5)	?	Yes	-	June 18	12
Bangkok	Yes	31/5 18	Yes	?	Yes	-	Apr 18	12
Seoul	-	31/5 18	Yes	?	Yes	-	June 18	12
Indonesia	-	31/5 18	Yes	?	Yes	-	June 18	8
China	Yes	31/5 18	Yes	?	?	-	?	?
Aarhus	-	31/5 18	Yes	?	Yes	YES	June 18	2
Sydney	Yes	31/5 18	Yes	?	-	-	Oct 18	6

Please let me know when you have completed the tasks mentioned in the table.

The address list has been updated:

Participating Centre	Country	CSI	Email ID	Interventional Radiologist	Email ID
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I wish you the best summer,

Morten