| | Clinical Trial<br>Summary Attachment<br>(based on RRF) | SA |
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| 1 | **Sponsor:** CHU de Bordeaux | |
| 2 | **Naming of the experimental drug(s):** SonoVUE | |
| 3 | **Naming of the experimental active(s) substance(s):** Hexafuorure Soufre | |
| 4<br>4.1<br><br><br>4.2<br>4.3 | **Study identification**<br>**Official Title:**<br>Dynamic Contrast Enhanced Ultrasound for Predict and Assess Rectal Cancer Response After Neo-adjuvant Chemoradiation<br><br>**Acronym:** RECT<br>**Unique Protocol ID:** CHUBX 2015/17 | |
| 5.1<br>5.2 | **ID EudraCT:** 2016-002589-30<br>**ID NCT :** NCT03068403 | |
| 6 | **Investigator(s):**<br>M. HOCQUELET Arnaud -<br>Imagerie médicale, radiologie diagnostique et thérapeutique -CHU DE BORDEAUX | |
| 7 | **Location(s):**<br>CHU de Bordeaux | |
| 8 | **Paediatric regulatory details if necessary: ☐yes / ☒no** | |
| 9<br><br><br><br><br><br>9.1 | **Trial status / Results Analysis stage:**<br>☒prematurely ended (Terminated)<br>☐withdrawn<br>☐no subjects recruited<br>☐only partial results are available<br>☐trial transitioned to CTIS and its results will be posted there<br><br>**Detailed reason:**<br>Target number of subject not reached | |
| 10<br>10.1<br><br>10.2 | **Notification of the end of the trial to the NCA : ☒yes / ☐no**<br>**ANSM:**<br><br>**RRF (Résumé du Rapport Final): Novembre 03 2020** | |
| 11<br>11.1<br>11.2<br>11.3 | **Study duration**<br>- First inclusion: June 18 2018<br>- Primary completion date: January 8 2019<br>- Study completion date January 8 2019 | 12. **Clinical Trial Phase / Type:** IV |
| 13<br>13.1<br>13.2<br>13.3 | **Population of trial subjects / Enrollment**<br>- **Number of subjects expected:** 20<br>- **Actual Number of subjects included in the trial: 2**<br>- **Actual Number of subjects analysed in the trial: NA** | |
| 14<br><br><br>14.1 | **Main objective:**<br>In this study we assessed D-CEUS to predict and assess pathological response in rectal cancer after neo-adjuvant CRT.<br><br>**Secondary objectives:**<br>- To evaluate the predictive value of other perfusion parameters (peak intensity, rise time, AUC of perfusion, mean transit time, time to peak, maximum perfusion slope, elimination rate) measured by quantitative contrast-enhanced ultrasound for the histopathological tumor response (TRG) in rectal cancer following neoadjuvant RCT (with or without first-line chemotherapy) | |

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| | - To evaluate the predictive value of changes in perfusion parameters measured by quantitative contrast-enhanced ultrasound for the histopathological tumor response (TRG) in rectal cancer following neoadjuvant RCT (with or without initial chemotherapy)<br>- To evaluate the predictive value of changes in perfusion parameters measured by quantitative contrast-enhanced ultrasound for the histopathological tumor response (TRG) in rectal cancer following first-line RCT<br>- To assess the correlation between changes in parameters measured by quantitative contrast-enhanced ultrasound and the evaluation of response to neoadjuvant RCT using MRI (MR TRG)<br>- To correlate perfusion parameters measured by quantitative contrast-enhanced ultrasound prior to neoadjuvant RCT with preoperative MR TNM staging (particularly lymph node status)<br>- To evaluate the reproducibility of perfusion parameter measurements between two radiologists: intra- and inter-observer reproducibility |
| 15 | **Research strategy:**<br>A pilote, prospective and exploratory study, single-center, open label, non-randomized,<br>With two arms :<br>A : Chemiotherapy and RCT<br>B : Only RCT |
| 16<br><br>16.1<br><br><br>16.2 | **Medical condition or disease studied:**<br>Rectal cancer<br><br>**Inclusion Criteria:**<br>- Histologically confirmed rectal carcinoma<br>- Stade ≥T2 and tumor size ≥3cm<br>- No detectable metastases<br>- Patient ≥ 18 years<br>- Patient information and written informed consent form signed<br>- Patient who can receive radiotherapy and chemotherapy<br>- Negative pregnancy test in women of childbearing potential<br>- Patient covered by a Social Security system<br><br>**Exclusion Criteria:**<br>- Indication for immediate surgery<br>- Primary tumor not measured at the MRI before inclusion<br>- Previous pelvic radiotherapy<br>- Contraindication to SONOVUE or MRI |
| 17 | **Experimental drug(s) studied (name, dose, route of administration, lot number):**<br>SonoVue, 8 µl/ml, 25mg vial for injection |
| 18 | **Treatment duration:**<br>Contrast agent injected during each contrast-enhanced ultrasound<br>Arm A : 3 ultrasounds for patients (Chemotherapy followed by RCT),<br>Arm B : 2 ultrasounds for patients Arm B (RCT alone) |
| 19 | **Reference Experimental drug(s) (name, dose, route of administration, lot number):** NA |
| 20<br><br>20.1<br><br><br>20.2 | **Evaluation criteria**<br><br>**Primary endpoint / Outcome:**<br>**Area under the echo-power curve (AUC)**<br>**Time Frame:** At inclusion, 3 months and 6 months visits<br><br>**Secondary endpoints / Outcomes:**<br>- **Peak enhancement (PE) - Time Frame:** At inclusion, 3 months and 6 months visits<br>- **Rise time (RT) - Time Frame: At inclusion, 3 months and 6 months visits**<br>- **Wash-in area under the curve (WiAUC) - Time Frame: At inclusion, 3 months and 6 months visits**<br>- **Mean transit time (mTT) - Time Frame: At inclusion, 3 months and 6 months visits**<br>- **Time to peak (TTP) - Time Frame:** At inclusion, 3 months and 6 months visits<br>- **Whash-in rate (WiR) - Time Frame:** At inclusion, 3 months and 6 months visits<br>- **Wash out rate (WoR) - Time Frame:** At inclusion, 3 months and 6 months visits<br>- **MRI assessed Tumor Response Grade (mrTRG) - Time Frame:** At inclusion, 3 months and 6 months visits<br>- **mrTNM staging - Time Frame:** At inclusion, 3 months and 6 months visits |

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| 21 | **Statistical analysis of the data** : NA |
| 22<br><br>22.1<br><br>22.2 | **Trial Summary – Results**<br><br>- **Outcomes / Efficacy evaluation: NA**<br><br>- **Adverses events / Security evaluation: One serious adverse event has been reported and considered not related to the study but to the disease under study.** |
| 23 | **Conclusion**<br>The target of 20 patients to be included in the study was not met because of a too low rate of recruitment.<br>Only 2 participants were included, without any analysis of the data.<br><br>In conclusion, no statistical analysis was performed. |
| 24 | **More Information**:<br>*Global Substantial Amendments:*<br>*Global Interruptions and re-starts:*<br>*Limitations & Caveats:* |
| 25 | **Publication(s):** |
| 26 | **Establishment date: July 30 2026** |